

Exhibit 47

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Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

- - - - - x
IN RE: VALSARTAN, LOSARTAN, AND : MDL NO. 2875
IRBESARTAN PRODUCTS LIABILITY :
LITIGATION, :
:
THIS DOCUMENT RELATES TO :
ALL ACTIONS :
- - - - - x

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Veritext Virtual Zoom Videotaped
deposition of RENA M. CONTI, Ph.D., taken on
Thursday, February 10, 2022, in Glenside,
Pennsylvania, commencing at 10:17 a.m. Eastern
Standard Time, before Jamie I. Moskowitz, a
Certified Court Reporter and Certified Livenote
Reporter.

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<div>Page 7</div> <div>1 A P P E A R A N C E S:</div> <div>2</div> <div>3 ULMER & BERNE LLP</div> <div>4 BY: JEFFREY D. GEOPPINGER, ESQUIRE</div> <div>5 jgeoppinger@ulmer.com</div> <div>6 312 Walnut Street - Suite 1400</div> <div>7 Cincinnati, Ohio 45202-4029</div> <div>8 513.698.5000</div> <div>9 Counsel for the Defendant AmerisourceBergen</div> <div>10</div> <div>11 ALSO PRESENT:</div> <div>12 JUSTIN BILY</div> <div>13 Legal Videographer</div> <div>14</div> <div>15</div> <div>16</div> <div>17</div> <div>18</div> <div>19</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> <div>25</div>	<div>Page 9</div> <div>1 REQUEST PAGE</div> <div>2</div> <div>3 INSTRUCTIONS NOT TO ANSWER:</div> <div>4 Page Line</div> <div>5 None</div> <div>6 REQUEST FOR PRODUCTION OF DOCUMENTS:</div> <div>7 Page Line Description</div> <div>8 None</div> <div>9 STIPULATIONS:</div> <div>10 Page Line</div> <div>11 None</div> <div>12 QUESTIONS MARKED:</div> <div>13 Page Line</div> <div>14</div> <div>15</div> <div>16</div> <div>17</div> <div>18</div> <div>19</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> <div>25</div>

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Page 10	Page 12
1 TABLE OF CONTENTS	1 to this arrangement and waive any objections to
2 RENA M. CONTI, Ph.D.	2 this manner of reporting. If there are any
3 Examination	3 objections, please state them at this time.
4 By Mr. Goldberg.....Page 12	4 * * *
5 Index of Exhibits.....Page 8	5 THE COURT REPORTER: Hearing no
6 Reporter Certificate.....Page 242	6 objections, I will swear in the witness.
7 Read and Sign.....Page 243	7 * * *
8	8 RENA CONTI, after having been first
9	9 duly sworn, was examined and testified as
10	10 follows:
11	11 * * *
12	12 THE COURT REPORTER: Okay, Counsel,
13	13 please proceed.
14	14 MR. GOLDBERG: Thank you.
15	15 EXAMINATION BY MR. GOLDBERG:
16	16 Q Good morning, Dr. Conti. My name is
17	17 Seth Goldberg. I'm with the law firm Duane Morris,
18	18 and we represent the ZHP parties in this action.
19	19 I'm going to be asking you questions during the
20	20 deposition today on behalf of all of the defendants
21	21 in the case, as well.
22	22 Can you state your name for the
23	23 record, and your current address?
24	24 A Sure, Rena Conti, 2 Overlea Way,
25	25 Glenside, PA 19038.
Page 11	Page 13
1 THE VIDEOGRAPHER: We are going on the	1 Q Okay. You've been deposed before,
2 record at 10:17 on February 10th, 2022. This	2 Dr. Conti?
3 is Media Unit Number 1 of the video recorded	3 A I have.
4 deposition of Rena Conti regarding the	4 Q You understand, throughout the day,
5 valsartan litigation.	5 I'm going to ask you questions. You're going to
6 My name's Justin Bilely from the firm	6 provide answers. And if -- during the day, if we
7 Veritext, and I'm the videographer. The court	7 can try not to talk over one another, that would be
8 reporter is Jamie Moskowitz from the firm	8 helpful.
9 Veritext.	9 Your counsel or plaintiff's counsel
10 All counsel will be noted on the	10 may assert objections from time to time. Unless
11 stenographic record. Will the court reporter	11 they instruct you not to answer, you're to answer
12 please swear in the witness, and then we can	12 the question, okay, notwithstanding the objection.
13 begin.	13 If you don't understand --
14 * * *	14 A I understand.
15 P R O C E E D I N G S	15 Q If you don't understand a question
16 THE COURT REPORTER: The attorneys	16 I've asked, please ask me to clarify it or rephrase
17 participating in this deposition acknowledge	17 it. If you answer it, we'll assume that you
18 that I am not physically present in the	18 understood it. Okay?
19 deposition room and that I will be reporting	19 A I understand. Thank you.
20 this deposition remotely.	20 Q If you need to take a break at any
21 They further acknowledge that, in lieu	21 time, no problem. Just ask.
22 of an oath administered in person, the witness	22 A Okay.
23 will verbally declare his testimony in this	23 Q Have you taken any medications this
24 matter is under penalty of perjury.	24 morning that may impair your testimony today?
25 The parties and their counsel consent	25 A I took a couple of Tylenol, but I

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<p style="text-align: right;">Page 14</p> <p>1 don't think that's going to --</p> <p>2 Q Hopefully -- okay.</p> <p>3 Why don't we talk a little bit about</p> <p>4 your professional background?</p> <p>5 Can you explain what your current</p> <p>6 position is at Boston University?</p> <p>7 A Sure.</p> <p>8 I am associate professor in the</p> <p>9 Department of Markets, Public Policy and Law at the</p> <p>10 business school at Boston University. It's called</p> <p>11 Questrom School of Business. In addition, I am</p> <p>12 co-director of the institute -- of an institute</p> <p>13 called Technology & Policy research Institute, which</p> <p>14 is an institute across the business school and the</p> <p>15 law school that focuses on issues related to</p> <p>16 technological innovation, its -- and its regulation.</p> <p>17 Q Are you -- are you currently teaching</p> <p>18 any courses?</p> <p>19 A Sadly, yes, I am. I am --</p> <p>20 Q What courses?</p> <p>21 A I am teaching Strategy in the</p> <p>22 Biopharmaceutical Industry --</p> <p>23 COURT REPORTER: I'm sorry. You're</p> <p>24 teaching...</p> <p>25 THE WITNESS: I teach Strategy in the</p>	<p style="text-align: right;">Page 16</p> <p>1 on drug pricing and regulation, and it's that report</p> <p>2 that the committee developed that is actually the --</p> <p>3 one of the textbooks that we use in my class.</p> <p>4 Q You said something about industry</p> <p>5 standard. I was trying to ask, industry standard</p> <p>6 for what? What -- you said something was the</p> <p>7 industry standard.</p> <p>8 A Oh, the materials that -- that I've</p> <p>9 developed for my course and developed in -- in other</p> <p>10 contexts during my research, are very widely used to</p> <p>11 teach about the industry, about the pharmaceutical</p> <p>12 industry.</p> <p>13 Q In terms of your expert consulting,</p> <p>14 you have an associate position at Greylock McKinnon?</p> <p>15 COURT REPORTER: Where?</p> <p>16 MR. GOLDBERG: Greylock McKinnon; is</p> <p>17 that correct?</p> <p>18 THE WITNESS: I'm sorry, is that a</p> <p>19 question?</p> <p>20 BY MR. GOLDBERG:</p> <p>21 Q Yes.</p> <p>22 A Okay. Right. So I have worked with</p> <p>23 Greylock McKinnon and Associates on -- on health</p> <p>24 litigation matters, again, largely in the</p> <p>25 pharmaceutical industry -- products, I guess, in the</p>
<p style="text-align: right;">Page 15</p> <p>1 Biopharmaceutical Industry. That is the class</p> <p>2 that I have taught for the better part of</p> <p>3 20 years.</p> <p>4 BY MR. GOLDBERG:</p> <p>5 Q What is that course about? Just give</p> <p>6 me a -- give me a thumbnail sketch of that course.</p> <p>7 A Sure.</p> <p>8 It's about the financing, organization</p> <p>9 and regulation of the pharmaceutical industry, and</p> <p>10 how firms in this industry, most notably the -- the</p> <p>11 pharmaceutical manufacturers themselves, innovate</p> <p>12 price, get reimbursed and generate revenue.</p> <p>13 Q Did you write a textbook for that</p> <p>14 course?</p> <p>15 A I'm in the process of writing a</p> <p>16 textbook now. Like I said, I have taught this class</p> <p>17 for the better part of 20 years, at</p> <p>18 Harvard University, at the University of Chicago and</p> <p>19 now at Boston University. And I developed many</p> <p>20 materials, including case studies, that are now the</p> <p>21 industry standard.</p> <p>22 I have a number of textbooks --</p> <p>23 Q Hang on --</p> <p>24 A Wait. Wait. So I was the economist</p> <p>25 on the National Academy of Science's recent report</p>	<p style="text-align: right;">Page 17</p> <p>1 pharmaceutical industry, again, for the better part</p> <p>2 of 20 years.</p> <p>3 Q And what do you do at</p> <p>4 Greylock McKinnon?</p> <p>5 A I provide expert services for -- in</p> <p>6 support of litigation.</p> <p>7 Q Do you do any consulting with</p> <p>8 Greylock McKinnon that is not litigation related?</p> <p>9 A No.</p> <p>10 Q Are there particular kinds of</p> <p>11 litigation that you work on for Greylock McKinnon?</p> <p>12 A Again, all of it's in -- on the</p> <p>13 pharmaceutical industry, related to pricing,</p> <p>14 reimbursement, coverage, competition and regulation.</p> <p>15 And I have been involved in a variety of antitrust</p> <p>16 matters, and a variety of -- of other types of legal</p> <p>17 matters.</p> <p>18 Q On a -- on a, you know, given day or</p> <p>19 given week, how many matters are you handling in</p> <p>20 your capacity as an -- this academic affiliate at</p> <p>21 Greylock?</p> <p>22 A It really depends on the time period</p> <p>23 and the year. Right now, I think I have maybe three</p> <p>24 cases that I'm working on in various forms.</p> <p>25 Q Well, are you working as an -- as an</p>

5 (Pages 14 - 17)

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 18</p> <p>1 expert in all three of those cases?</p> <p>2 A Yes.</p> <p>3 Q Okay. And are those three cases</p> <p>4 products liability cases? Are they antitrust cases?</p> <p>5 What's the subject matter of those cases?</p> <p>6 A One of them is a liability case,</p> <p>7 and -- well, actually -- yeah. One of them is a</p> <p>8 liability case, and two others are antitrust cases.</p> <p>9 Q Generally, can you -- can you describe</p> <p>10 the mix on a percentage basis, between antitrust,</p> <p>11 patent, products liability, that you -- that you</p> <p>12 generally have?</p> <p>13 A So do you mean in relation to the work</p> <p>14 that I do at -- with Greylock McKinnon --</p> <p>15 Q Yes.</p> <p>16 A -- or other -- okay.</p> <p>17 Q Well, are you doing expert work</p> <p>18 outside of Greylock McKinnon?</p> <p>19 A Yes, I am.</p> <p>20 Q Okay. Is that -- I guess we'll --</p> <p>21 we'll get to your CV, and maybe you can show me on</p> <p>22 your CV where that is.</p> <p>23 But why don't we take it first with</p> <p>24 Greylock McKinnon, where your -- what the case mix</p> <p>25 is from antitrust, patents and other subject</p>	<p style="text-align: right;">Page 20</p> <p>1 Are you -- do you have an independent expert</p> <p>2 consulting firm that you're just doing</p> <p>3 independently?</p> <p>4 A I am working on a number of matters</p> <p>5 that Greylock McKinnon has conflicts with, and</p> <p>6 I'm -- they are largely either business disputes</p> <p>7 between pharmaceutical firms --</p> <p>8 COURT REPORTER: Between what?</p> <p>9 THE WITNESS: Between pharmaceutical</p> <p>10 firms.</p> <p>11 COURT REPORTER: Uh-huh.</p> <p>12 THE WITNESS: Or matters related to</p> <p>13 government work that -- where I am serving as</p> <p>14 an expert and there are government agencies</p> <p>15 involved.</p> <p>16 BY MR. GOLDBERG:</p> <p>17 Q Can you describe what that -- can you</p> <p>18 give us a little bit more detail about what those</p> <p>19 kinds of matters are?</p> <p>20 MR. HONIK: Dr. Conti -- Dr. Conti,</p> <p>21 let me instruct you that while Mr. Goldberg's</p> <p>22 questions are fine, not to reveal any matters,</p> <p>23 particularly in the litigation sphere, in which</p> <p>24 there may not have been a normal date to</p> <p>25 disclose your involvement. And so be very</p>
<p style="text-align: right;">Page 19</p> <p>1 matters?</p> <p>2 A I don't quite understand what you mean</p> <p>3 by "patent."</p> <p>4 Q Patent, patent, patent or intellectual</p> <p>5 property. Are you doing any expert work in</p> <p>6 intellectual property matters?</p> <p>7 A Not -- so patents are obviously an</p> <p>8 important part of the industry. But -- and they are</p> <p>9 related to the work that I'm doing, but I'm not</p> <p>10 doing any patent litigation work, if that is what</p> <p>11 you're asking.</p> <p>12 Q Yeah. So I'm asking, what is the --</p> <p>13 you know, the -- the makeup of the different subject</p> <p>14 matters that you're working on as an expert, as a</p> <p>15 general matter. You said antitrust. You said</p> <p>16 products liability. Are there other types of</p> <p>17 matters that you work on?</p> <p>18 A Okay. So at Greylock McKinnon, I'm</p> <p>19 largely working half and half on product liability</p> <p>20 and antitrust. I would say I have increasingly</p> <p>21 worked on product liability over the past couple of</p> <p>22 years, and -- but generally, there's a mix of that</p> <p>23 now.</p> <p>24 Q And explain what your expert work is</p> <p>25 when you're doing it not through Greylock McKinnon.</p>	<p style="text-align: right;">Page 21</p> <p>1 circumspect about that. Thank you.</p> <p>2 THE WITNESS: Thank you.</p> <p>3 On the government investigations</p> <p>4 and -- I am serving as an expert and have</p> <p>5 served as an expert in the past. And I can't</p> <p>6 provide any details.</p> <p>7 BY MR. GOLDBERG:</p> <p>8 Q Are there matters that you worked in</p> <p>9 terms of government investigations in the past that</p> <p>10 you can provide details about what the -- what the</p> <p>11 subject matter is of the investigation? Are you</p> <p>12 investigating cGMP practices? Are you investigating</p> <p>13 fraud? Are you investigating, you know, something</p> <p>14 related to the business? I'm just trying to get a</p> <p>15 sense of what you do as an expert in government</p> <p>16 investigation.</p> <p>17 A Sure. So every single day, all day</p> <p>18 long, all I do is think about the financing, the</p> <p>19 organization and the regulation of the</p> <p>20 pharmaceutical industry. So you can kind of fairly</p> <p>21 surmise from that that the work that I'm doing,</p> <p>22 either in business disputes between industry members</p> <p>23 is related to financing, organization and regulation</p> <p>24 of these products, and in the government work that I</p> <p>25 do, again, it's all related to financing,</p>

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<p style="text-align: right;">Page 22</p> <p>1 organization and regulation.</p> <p>2 I have been a special consultant to</p> <p>3 the Office of Generic Drugs for years, and have been</p> <p>4 involved in the regulation of pharmaceuticals by the</p> <p>5 Food and Drug Administration for a long time.</p> <p>6 And so a lot of the -- a lot of the</p> <p>7 work that I work on for government agencies is</p> <p>8 related to the regulation of these products.</p> <p>9 Q Is there a particular aspect of the</p> <p>10 regulation of these products that you focus on? And</p> <p>11 when you're -- let me qualify that. Regulation of</p> <p>12 pharmaceutical products that you focus on?</p> <p>13 A So I would say I have two broad</p> <p>14 expertise. The first is on pricing of these</p> <p>15 products; how it is priced by the pharmaceutical</p> <p>16 industry themselves, what are the factors that lead</p> <p>17 to prices being high, changing over time, increasing</p> <p>18 or decreasing with competition, both in the branded</p> <p>19 and specialty -- or branded and generic market.</p> <p>20 And then the second broad category of</p> <p>21 expertise is on competition, and specifically what</p> <p>22 are the factors that drive pharmaceutical companies</p> <p>23 to enter specific types of markets, particularly</p> <p>24 generic markets; what are the conditions upon which</p> <p>25 they can enter those markets; how does competition</p>	<p style="text-align: right;">Page 24</p> <p>1 and others.</p> <p>2 Q Okay. Got it.</p> <p>3 Back to the expert stuff, in terms of</p> <p>4 working as an expert on behalf of plaintiffs, on</p> <p>5 behalf of defendants, do you -- do you do more of</p> <p>6 one or the other?</p> <p>7 A So I have worked on the defendant</p> <p>8 side, largely in business disputes between different</p> <p>9 firms. In those cases, matters largely related to</p> <p>10 production of products and the regulation of those</p> <p>11 products have been domain.</p> <p>12 And then I would say -- I mean,</p> <p>13 obviously, in the government work I've done, it's</p> <p>14 largely been on the side of the government and</p> <p>15 taxpayers, consumers, that are insured by the</p> <p>16 government.</p> <p>17 And then -- and then I have done</p> <p>18 plaintiff's work on -- largely on antitrust matters.</p> <p>19 Q And in products work, are you on</p> <p>20 plaintiff's side more than defendant's side?</p> <p>21 A I'm sorry. I didn't hear the first</p> <p>22 part.</p> <p>23 Q In products -- in products liability</p> <p>24 matters, or consumer class action matters, are you</p> <p>25 on plaintiff's side more than defendant's side?</p>
<p style="text-align: right;">Page 23</p> <p>1 evolve over time; and to what extent do regulatory</p> <p>2 agencies support entry and sustained competition</p> <p>3 over time.</p> <p>4 Q I just want to come back -- I'd just</p> <p>5 like to clarify one thing.</p> <p>6 Going back to when you were talking</p> <p>7 about your coursework, and you -- the -- the</p> <p>8 materials that you said, you know, are used and have</p> <p>9 become an industry standard, when you -- when you're</p> <p>10 talking about the industry standard, you're saying</p> <p>11 the industry standard for teaching this stuff at</p> <p>12 universities. Is that -- is that what you mean?</p> <p>13 A Well, right. So many of my articles</p> <p>14 that I've published on the pricing of these products</p> <p>15 and the regulation of these products are used by</p> <p>16 myself to teach, but are also used by many other</p> <p>17 experts in the field to teach about this industry.</p> <p>18 And that's actually one of the conditions of tenure,</p> <p>19 is that there is an industry standard that -- that</p> <p>20 is met.</p> <p>21 And then I have developed coursework</p> <p>22 for materials that are used for teaching, case</p> <p>23 studies, that type of stuff, that are used by</p> <p>24 myself, and they are used by Harvard University</p> <p>25 professors. And they are used by Wharton professors</p>	<p style="text-align: right;">Page 25</p> <p>1 A I've largely worked on the plaintiff's</p> <p>2 side on those matters.</p> <p>3 Q Have you represented any defendants</p> <p>4 in -- as an -- as an expert, in a products liability</p> <p>5 action or consumer class action?</p> <p>6 A What do you mean by "consumer class</p> <p>7 action?" I'm sorry.</p> <p>8 Q Like -- like the claims that we're</p> <p>9 here for today, the economic loss claim. Consumers</p> <p>10 are claiming they should get a refund for a product.</p> <p>11 A Right. So I'm only -- I think I have</p> <p>12 three cases right now, one settled, on products</p> <p>13 liability. Each one of those cases, I was working</p> <p>14 on the plaintiff's side.</p> <p>15 Q So in your -- your expert consulting</p> <p>16 experience, you've done three products liability</p> <p>17 cases; is that correct?</p> <p>18 A Right, that I can talk about. Right.</p> <p>19 Q And of those three, all three were on</p> <p>20 behalf of plaintiffs?</p> <p>21 A Correct.</p> <p>22 Q How many other products liability</p> <p>23 matters have you worked on that you can't talk</p> <p>24 about?</p> <p>25 A At least one that comes to mind.</p>

7 (Pages 22 - 25)

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<p style="text-align: right;">Page 26</p> <p>1 Q And in that one, can you tell us 2 whether it's on behalf of plaintiffs or defendants? 3 A It was for the government. 4 Q Okay. In 2021, since we just finished 5 the year, how much of your income was generated from 6 your work as an expert witness versus your income as 7 a professor? 8 A Somewhere maybe around a quarter. 9 Q Can you quantify that in dollars, what 10 that expert work looks like on an annual basis? 11 A Do you mean in 2021? 12 Q Yes, sure. 13 A Okay. So pandemic year, I think I 14 made approximately \$100,000, maybe \$80,000, 15 somewhere around there, in 2021. Much of that was 16 for cases that I worked on in previous years, not 17 in -- in 2021. 18 Q Has the pandemic caused you to have 19 fewer cases or work? 20 A Sadly, it's the reverse. All I do is 21 sit in my house and work. I know you all probably 22 feel the same way. 23 Q We all share that -- we all share that 24 experience that we're working way more due to the 25 pandemic, especially in litigation.</p>	<p style="text-align: right;">Page 28</p> <p>1 Greylock and your first meetings with plaintiffs' 2 counsel? 3 A I think it was the month, or maybe the 4 month previous, to when the pandemic started. 5 Q February of '20? 6 A February or March. I remember it was 7 a very gray, cold day in Boston. 8 Q Do you recall who the lawyers were for 9 the plaintiffs that you met with for the first time 10 when you met -- had that first meeting in this 11 matter? 12 A I think Ruben Honik and 13 Conlee Whiteley and Layne Hilton were on that first 14 call. 15 Q Have you -- 16 A Maybe misremembering -- 17 THE COURT REPORTER: I'm sorry, 18 Ms. who? 19 THE WITNESS: Misremembering. 20 THE COURT REPORTER: Misremembering? 21 THE WITNESS: Misremembering. Sorry. 22 My English. 23 MR. HONIK: It's a thing, not a 24 person. 25 THE WITNESS: Exactly.</p>
<p style="text-align: right;">Page 27</p> <p>1 A I'm hoping to not be like that in 2 2022. 3 Q Yeah. In terms of the -- the business 4 disputes where you've been an expert, have you 5 represented pharmaceutical companies in those 6 business disputes? 7 A Yes. Again, every single day, all I 8 do is think about this industry. So in those 9 matters, they've been pharmaceutical companies. 10 Q Are there -- are they generic 11 companies or branded companies? 12 A Both. 13 Q Were any of the companies that you've 14 represented in these matters, defendants in this 15 case? 16 A No. 17 Q Have you -- let's talk about your 18 retention in this matter. How did you -- how did 19 you come about being retained in this matter? 20 A I was contacted by one of the 21 principals at Greylock McKinnon and Associates, and 22 asked if I would be interested in discussing with 23 the attorneys the general outlines of the -- of the 24 matter. 25 Q When was that first contact at</p>	<p style="text-align: right;">Page 29</p> <p>1 BY MR. GOLDBERG: 2 Q Well, whoever those plaintiffs' 3 counsel were, had you known any of them before that 4 first meeting? 5 A No. 6 Q Had you worked with any of the 7 plaintiffs' counsel that are on -- on the 8 plaintiffs' executive committee in this case prior 9 to starting work on this matter? 10 A Not -- not that I can recall. 11 Q Do you know if Greylock McKinnon had a 12 prior relationship with any of the lawyers that 13 represent the plaintiffs in this matter? 14 A I don't know. 15 Q Do you have any matters currently 16 pending with any of the lawyers that represent 17 plaintiffs in this matter, any other matters that 18 you're working on? 19 A I am sorry. What do you mean by 20 "currently pending"? 21 Q Are you an expert in any cases that 22 are currently pending where the lawyers who are 23 plaintiffs in this case are representing parties in 24 that case? 25 A I'm sorry. I don't -- I don't know</p>

8 (Pages 26 - 29)

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<p style="text-align: right;">Page 30</p> <p>1 what you mean by "currently pending".</p> <p>2 Q Okay. Are -- are you doing expert</p> <p>3 work in any other case where the lawyers who</p> <p>4 represent the plaintiffs in this case are involved?</p> <p>5 A Yes.</p> <p>6 Q What case is that?</p> <p>7 MR. HONIK: Let me caution you,</p> <p>8 Dr. Conti, that to the extent that there's no</p> <p>9 disclosure requirement in those matters, you</p> <p>10 should not reveal that today.</p> <p>11 THE WITNESS: Thank you. I cannot</p> <p>12 provide any details.</p> <p>13 BY MR. GOLDBERG:</p> <p>14 Q Which lawyers in plaintiffs' committee</p> <p>15 are involved in that case?</p> <p>16 MR. HONIK: Let me instruct you not to</p> <p>17 answer that for the same reason posited</p> <p>18 previously. It's effectively the same question</p> <p>19 and would reveal something -- excuse me -- and</p> <p>20 would reveal or disclose something that doesn't</p> <p>21 require to be disclosed at present. Thank you.</p> <p>22 THE WITNESS: I'm sorry. I cannot</p> <p>23 provide an answer.</p> <p>24 MR. GOLDBERG: Counsel, you can mark</p> <p>25 this portion of the transcript "highly</p>	<p style="text-align: right;">Page 32</p> <p>1 answer and reveal the type of matter, litigated</p> <p>2 matter.</p> <p>3 BY MR. GOLDBERG:</p> <p>4 Q In that matter, have you been asked to</p> <p>5 render an opinion that's similar to the opinion</p> <p>6 you've been -- provided in this case?</p> <p>7 MR. HONIK: Object to the form.</p> <p>8 THE WITNESS: Are you asking whether</p> <p>9 that matter is on the pharmaceutical industry</p> <p>10 and its regulation and financing?</p> <p>11 BY MR. GOLDBERG:</p> <p>12 Q Sure. Let's start with that.</p> <p>13 A Yes. Everything --</p> <p>14 MR. HONIK: Excuse me.</p> <p>15 THE WITNESS: Go ahead.</p> <p>16 MR. HONIK: Without waiving the</p> <p>17 objection, I'll permit you to answer that and</p> <p>18 only that question.</p> <p>19 THE WITNESS: Thank you.</p> <p>20 Everything I work on in my teaching,</p> <p>21 in my research and in the expert work that I</p> <p>22 provide to the government and to other</p> <p>23 entities, is related to the financing,</p> <p>24 organization and regulation of the</p> <p>25 pharmaceutical industry.</p>
<p style="text-align: right;">Page 31</p> <p>1 confidential" so that it doesn't have to be</p> <p>2 disclosed outside of this matter, but I think</p> <p>3 we're entitled to know if Dr. Conti is working</p> <p>4 for the lawyers who represent the plaintiffs in</p> <p>5 this case in another matter.</p> <p>6 MR. HONIK: She's already answered</p> <p>7 affirmatively to that question. But your</p> <p>8 pending question, to which I objected and</p> <p>9 instructed her not to answer, is -- is nearly a</p> <p>10 backdoor way of disclosing formally her</p> <p>11 involvement as an expert in cases in which</p> <p>12 there's not presently a disclosure requirement.</p> <p>13 Accordingly, I've instructed her, and</p> <p>14 she's followed it, not to identify the lawyers</p> <p>15 because that identification effectively reveals</p> <p>16 the matter in which she's working. That's the</p> <p>17 basis. So please ask another question.</p> <p>18 BY MR. GOLDBERG:</p> <p>19 Q That matter, is that a products</p> <p>20 liability matter?</p> <p>21 MR. HONIK: I instruct you not to</p> <p>22 answer.</p> <p>23 BY MR. GOLDBERG:</p> <p>24 Q Is it a -- is it an antitrust matter?</p> <p>25 MR. HONIK: I instruct you not to</p>	<p style="text-align: right;">Page 33</p> <p>1 THE COURT REPORTER: Of the</p> <p>2 pharmacy -- of the pharmacy...</p> <p>3 THE WITNESS: Of the pharmaceutical</p> <p>4 industry.</p> <p>5 THE COURT REPORTER: Thank you.</p> <p>6 THE WITNESS: Thank you.</p> <p>7 BY MR. GOLDBERG:</p> <p>8 Q When did you begin to work on that</p> <p>9 matter?</p> <p>10 A I'm sorry, on -- on the industry?</p> <p>11 Q No, on the matter that we've been</p> <p>12 discussing that you're working for plaintiffs'</p> <p>13 counsel in.</p> <p>14 MR. HONIK: I'll instruct you not to</p> <p>15 answer that question for the same reason.</p> <p>16 Seth, respectfully, these are just</p> <p>17 backdoor ways to try to get at your essential</p> <p>18 question, which is, tell me the other cases</p> <p>19 that you're involved in. And I won't allow</p> <p>20 Dr. Conti to reveal that.</p> <p>21 MR. GOLDBERG: Well, I -- I disagree.</p> <p>22 I don't need to know the name of the case. I</p> <p>23 don't need to know the names of the other</p> <p>24 parties, but I do think we're entitled to know</p> <p>25 what Dr. Conti is doing for plaintiffs' counsel</p>

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Page 34	Page 36
<p>1 in this case in other matters.</p> <p>2 MR. HONIK: Yeah, I don't agree. And</p> <p>3 moreover, I don't understand the last part of</p> <p>4 your observation. I have permitted you to ask</p> <p>5 her many questions about all of the matters</p> <p>6 that she's involved with, for whom she's doing</p> <p>7 these in terms of segments of industry and</p> <p>8 otherwise.</p> <p>9 But you know and I know that if you're</p> <p>10 involved as an expert consultant in a case in</p> <p>11 which the date for disclosure of experts has</p> <p>12 not yet arrived, that that is information that</p> <p>13 can't be revealed. So please move on.</p> <p>14 BY MR. GOLDBERG:</p> <p>15 Q How much money have you made from</p> <p>16 plaintiffs' counsel in that case?</p> <p>17 MR. HONIK: Without waiving the</p> <p>18 objection, you can answer. I think you did,</p> <p>19 didn't you?</p> <p>20 THE WITNESS: Thank you. None.</p> <p>21 BY MR. GOLDBERG:</p> <p>22 Q Do you have your retention in that</p> <p>23 case through Greylock McKinnon?</p> <p>24 A Yes.</p> <p>25 Q Are you charging in that matter the</p>	<p>1 generic entry in product markets, and have</p> <p>2 thought a lot about -- I have thought about and</p> <p>3 also researched the entry of manufacturers in</p> <p>4 this particular market.</p> <p>5 BY MR. GOLDBERG:</p> <p>6 Q When you say," in this particular</p> <p>7 market," what were you -- define what you mean by</p> <p>8 "in this particular market."</p> <p>9 A In the valsartan market.</p> <p>10 Q When you were studying or researching</p> <p>11 valsartan in connection with your interest in heart</p> <p>12 disease, what was the nature of the research?</p> <p>13 A Pricing, promotion and --</p> <p>14 THE COURT REPORTER: And -- and what?</p> <p>15 THE WITNESS: And access to these</p> <p>16 products.</p> <p>17 BY MR. GOLDBERG:</p> <p>18 Q What do you mean by "access"?</p> <p>19 A Patient use.</p> <p>20 Q Were you looking at it from an</p> <p>21 efficacy standpoint?</p> <p>22 A Safety and efficacy are both part -</p> <p>23 are both determinants of access. So I guess,</p> <p>24 generally, yes.</p> <p>25 Q But at that -- at that time, you</p>
Page 35	Page 37
<p>1 same fee, hourly fee, that you're charging in this</p> <p>2 matter?</p> <p>3 A I don't know.</p> <p>4 Q Have you generated an invoice yet in</p> <p>5 that matter?</p> <p>6 A No.</p> <p>7 Q Okay. Going back to the beginning of</p> <p>8 your retention in this case, prior to being retained</p> <p>9 or at least meeting plaintiffs' counsel in February,</p> <p>10 March 2020, had you done any research into</p> <p>11 valsartan?</p> <p>12 A Yes.</p> <p>13 Q In -- in what capacity did you do</p> <p>14 research into valsartan prior to that February,</p> <p>15 March 2020 time period?</p> <p>16 A In two separate capacities. The first</p> <p>17 is that I have a longstanding interest in some types</p> <p>18 products --</p> <p>19 COURT REPORTER: In some what?</p> <p>20 THE WITNESS: In some types of</p> <p>21 pharmaceutical products, which include drugs</p> <p>22 that are used to treat heart disease, valsartan</p> <p>23 being one of them, but there are many others.</p> <p>24 And then, in the other capacity, I</p> <p>25 have spent a fair amount of time thinking about</p>	<p>1 became generally familiar with the safety and</p> <p>2 efficacy of valsartan at that time?</p> <p>3 A I think I would think -- I think about</p> <p>4 that differently as an economist. So I am</p> <p>5 interested, again, in the pricing and the</p> <p>6 reimbursement and in the utilization of these drugs.</p> <p>7 Safety and efficacy of products are one of the</p> <p>8 determinants -- or two of the determinants of people</p> <p>9 using these products.</p> <p>10 Q Okay. So you -- you were kind of</p> <p>11 thinking about how many people are using it, the</p> <p>12 number of people who are using it, and that's sort</p> <p>13 of indicative of its safety and efficacy in some</p> <p>14 way?</p> <p>15 A No.</p> <p>16 Q Okay. Do you want to explain?</p> <p>17 A Sure.</p> <p>18 So I was thinking about the pricing of</p> <p>19 this product market, which included the -- the</p> <p>20 valsartan products, but not only the valsartan</p> <p>21 products. I've been thinking about the</p> <p>22 reimbursement of those products, so who pays what</p> <p>23 for them. And then I have -- I researched the use</p> <p>24 of those products, so what determines the use of</p> <p>25 those products, what are the general patterns of use</p>

10 (Pages 34 - 37)

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<p style="text-align: right;">Page 38</p> <p>1 in national prescriptions, in dispensing of 2 prescriptions in certain -- by certain -- 3 COURT REPORTER: I'm sorry. In 4 certain? 5 THE WITNESS: Sorry. In certain 6 markets, et cetera. 7 BY MR. GOLDBERG: 8 Q And by "these products," you're -- you 9 said it's more than valsartan. Are you talking 10 hypertension products generally, or -- or is it 11 heart disease products generally? 12 A Correct, drugs that are used to treat 13 heart disease. 14 Q What was the timeframe of doing this 15 kind of research? 16 A So I would say it overlapped with 17 my -- the completion of my dissertation. So I 18 finished my dissertation in 2007. I was researching 19 the use of these products and their pricing before I 20 finished my dissertation, so probably 2003, 2005. 21 And then it continued on from there. 22 Similarly, I was very -- I've been 23 very interested in competition, so when these 24 products are expected to experience generic entry, 25 undergo patent expiration; what types of product --</p>	<p style="text-align: right;">Page 40</p> <p>1 A No. This is just part of, again, the 2 work -- this is all part of understanding a little 3 bit more -- understanding this market. I was a 4 chemistry major when I entered college, so I 5 actually know what they are. So I -- I am familiar 6 with what they are before I was an economist. 7 Q And in between 2010 and 2020, did you 8 do any particular research on the occurrence of NDMA 9 or NDEA in pharmaceutical products? 10 A Okay. I'm sorry. Can you restate the 11 question or just -- just ask the question again? 12 Q Sure. 13 Between 2010, when you said that 14 article -- that article came out, and February 2020, 15 did you do any research in -- in the area of the 16 occurrence of NDMA or NDEA in pharmaceutical 17 products? 18 A Right. So there's a various body of 19 literature that was developing since, I think, at 20 least the early 2000s on -- and actually, probably, 21 before then, on -- on chemical contaminants that are 22 harmful to human health. I did some coursework on 23 that in -- at Harvard when I was finishing my -- 24 when I was doing my Ph.D. And I have been 25 interested in the topic especially since -- since I</p>
<p style="text-align: right;">Page 39</p> <p>1 or what types of firms enter into these markets; how 2 much competition is there; to what extent do these 3 prices go down over time; who uses these types of 4 products. I think I've been thinking about that 5 since at least 2010, 2011. 6 Q How about nitrosamines? Are you 7 familiar with nitrosamines? 8 A Yes. 9 Q Prior to the February, March 2020 10 timeframe, had you done any work in connection with 11 nitrosamines? 12 A Yes. There was -- President Bush had 13 a council on cancer that released a report in 2010 14 about toxins, and specifically chemicals that can 15 cause DNA damage and other types of human health 16 harms that people might be exposed to in the 17 United States. I read that report when it came out. 18 I have been generally interested in -- in 19 determining -- in chemicals that might impact 20 consumer health. 21 As an expert in pharmaceutical 22 economics and policy, this is kind of part of my -- 23 my job, is to understand what these things are. 24 Q Have you done any -- authored any 25 articles relating to nitrosamines?</p>	<p style="text-align: right;">Page 41</p> <p>1 did my dissertation. 2 Q All right. I think you said you 3 finished your dissertation before 2010? 4 A Right. I finished -- my dissertation 5 was awarded in -- or my Ph.D. was awarded in 2007. 6 Q All right. My -- my question was -- 7 I'm trying to be little more specific. 8 A Uh-huh. 9 Q My question was, since 2010, between 10 2010 and February of 2020, have you done any focused 11 research on the occurrence of NDMA and NDEA, in 12 particular, in pharmaceutical drugs? 13 A So I don't know what you mean by 14 "focused research." 15 Q Well, has -- has the particular focus 16 of research that you've done been the occurrence of 17 NDMA or for NDEA in pharmaceutical drugs? 18 A So -- so again, the occurrence of 19 these products and their threat to human health as 20 part of the pharmaceutical industry is something 21 that I have been aware of for a long time. And 22 because of product contamination and adulteration in 23 other product categories, not in valsartan, but in 24 other drugs since at least 2007, 2008, that involve 25 products made by Ranbaxy, products made at the Cidra</p>

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Page 42	Page 44
<p>1 plant, products made by Mylan, I am aware that there 2 are a variety of chemicals that can contaminate 3 pharmaceuticals and are harmful to human health. 4 And NDMA is one of those products. It's not the 5 only one. 6 Q And I'm asking about NDMA. Have you 7 studied NDMA prior to February of 2020? 8 A NDMA and other products that have come 9 up in my work between 2010 and 2020. Just like -- 10 so, again, I -- if you are an expert in this 11 industry, you know that there have been some very 12 significant quality manufacturing lapses in 13 pharmaceutical products. That includes contaminated 14 Heparin. It includes the products that were made at 15 Ranbaxy and ultimately at Mylan as well, and the 16 products that were made at the Cidra plant -- 17 COURT REPORTER: At the what? 18 THE WITNESS: By Glaxo -- by 19 GlaxoSmithKline. 20 COURT REPORTER: I'm sorry. That were 21 made at the... 22 THE WITNESS: Cidra plant at -- owned 23 by GlaxoSmithKline in Puerto Rico. 24 There have also been other lapses in 25 quality and in manufacturing that have occurred</p>	<p>1 Q Do you have Tab 66, what we have 2 marked as Conti 1, in front of you? 3 A I do. If you can just give me a 4 second to read it, please. 5 Q Okay. This is your retention 6 agreement with plaintiffs' counsel in this case? 7 A This is GMA's retention agreement with 8 the attorneys on my behalf. 9 THE COURT REPORTER: I'm sorry? 10 THE WITNESS: On my behalf. 11 BY MR. GOLDBERG: 12 Q And it says that, in the first 13 paragraph, that plaintiffs' executive committee has 14 retained Greylock McKinnon Associates to provide 15 consulting on economic issues and other related 16 services. 17 What -- what are the related services 18 that -- that you're providing? 19 A I don't know. 20 Q It goes on to say that you're going 21 to -- you've been retained to provide expert 22 testimony as it relates to issues of the calculation 23 of damages. 24 A I see that. 25 Q Are -- are you -- do you understand</p>
Page 43	Page 45
<p>1 particularly around 2010, 2011, 2012. And I 2 have been very interested in what exactly those 3 quality lapses were and -- and what are the 4 nature of the -- what are the harms to human 5 health of those types of lapses. 6 So I am aware of nitrosamines, in 7 addition to many other chemicals, being harmful 8 to human health and have been aware of that 9 during this time period. 10 MR. GOLDBERG: Can we pull up Tab 66? 11 BY MR. GOLDBERG: 12 Q Dr. Conti, I want to show you your 13 retention agreement in this case. I don't think you 14 need to take the time to go through the binder, but 15 if you want to, I just want to pull this up and mark 16 this as Conti 1. 17 (Whereupon, Exhibit Conti 1 was marked 18 for Identification.) 19 BY MR. GOLDBERG: 20 Q This is -- can you see that okay? You 21 have it up on the screen? 22 A Yeah. I'm going to go get my binder. 23 Q It's going to be Tab 66 in that 24 binder. 25 A Okay. Great.</p>	<p>1 that that -- that to be the scope of your testimony, 2 the calculation of damages? 3 MR. HONIK: Object to the form and to 4 the extent that it calls for a legal expert 5 opinion. 6 You may answer. 7 THE WITNESS: I have produced a report 8 that is calculating damages in this matter. 9 BY MR. GOLDBERG: 10 Q So the answer is, yes, you understand 11 the scope of your work to be in relation to the 12 calculation of damages? 13 MR. HONIK: Same objection. 14 You may answer. 15 THE WITNESS: Thank you. 16 So up until this period in time, what 17 I have largely worked on in this matter is 18 related to the calculation of damages. 19 MR. GOLDBERG: You can take that down, 20 put that aside. 21 BY MR. GOLDBERG: 22 Q You generated a report in this matter 23 in November of 2021. Can you describe, generally, 24 what the process was for putting together that 25 report?</p>

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<p style="text-align: right;">Page 46</p> <p>1 A I reviewed data. We --</p> <p>2 THE COURT REPORTER: I'm sorry,</p> <p>3 Doctor. Can you repeat that?</p> <p>4 THE WITNESS: Sure.</p> <p>5 I discussed with the attorneys the</p> <p>6 availability of data to calculate damages in</p> <p>7 this matter, and also theories of liability</p> <p>8 that would determine how we calculated</p> <p>9 damages -- or how I calculated damages. I</p> <p>10 worked with my staff to -- and with -- and with</p> <p>11 the attorneys, to cull materials that would be</p> <p>12 helpful in the calculation of damages. And I</p> <p>13 also reviewed regulatory documents and other</p> <p>14 facts that are relevant to the calculation of</p> <p>15 damages.</p> <p>16 And there's -- hold on. And there was</p> <p>17 lots of drafting, analysis, redrafting and</p> <p>18 finally, the final report.</p> <p>19 BY MR. GOLDBERG:</p> <p>20 Q How long do you think it took to</p> <p>21 generate the report from when you started to work --</p> <p>22 work on it?</p> <p>23 MR. HONIK: Seth, can we agree that</p> <p>24 when you use the word, "report," you're</p> <p>25 referring to the expert declaration of</p>	<p style="text-align: right;">Page 48</p> <p>1 pretty intently, at least starting over the summer.</p> <p>2 Q Over which summer?</p> <p>3 A Last summer, 2021.</p> <p>4 Q You mentioned the staff. How big was</p> <p>5 your staff for this matter, and who were they?</p> <p>6 A The people that I have worked most</p> <p>7 closely with are Bennett Erickson and Sarah Stone,</p> <p>8 both employees at Greylock McKinnon, both people</p> <p>9 that I work with pretty closely, generally. There</p> <p>10 might be some other staff that I don't know as well</p> <p>11 that have worked on this case.</p> <p>12 Q Do you have a sense of how much time</p> <p>13 Bennett put into this matter?</p> <p>14 A No. Bennett's worked a lot on this</p> <p>15 matter. But I -- I don't know. I don't see his</p> <p>16 billings.</p> <p>17 Q Do you see anybody's billings for this</p> <p>18 matter, or does that all go to Greylock admins?</p> <p>19 A I am very grateful for the work that</p> <p>20 Greylock does, and no, I don't see any of the</p> <p>21 billings. I don't -- I'm not involved in any of the</p> <p>22 administration.</p> <p>23 Q Do you have a sense of how many hours</p> <p>24 you put into the declaration?</p> <p>25 A Frankly, no.</p>
<p style="text-align: right;">Page 47</p> <p>1 Dr. Conti --</p> <p>2 MR. GOLDBERG: Yes.</p> <p>3 MR. HONIK: -- of November 10th of</p> <p>4 last year.</p> <p>5 MR. GOLDBERG: Yes, the expert</p> <p>6 declaration.</p> <p>7 MR. HONIK: Thank you.</p> <p>8 THE WITNESS: I'm sorry. Can you ask</p> <p>9 me the question --</p> <p>10 MR. HONIK: How long did it take you?</p> <p>11 That's what he asked.</p> <p>12 THE WITNESS: To generate the report,</p> <p>13 correct?</p> <p>14 BY MR. GOLDBERG:</p> <p>15 Q Yes.</p> <p>16 A Okay. Many months.</p> <p>17 Q How many months?</p> <p>18 A A lot. A lot of time because we were</p> <p>19 waiting -- we were discussing. We were waiting for</p> <p>20 data. We were -- and then calculating damages and</p> <p>21 then writing the report.</p> <p>22 Q Many, a lot, do you have -- was it</p> <p>23 10 months, more than 10 months?</p> <p>24 A I would say -- I mean, we -- I was</p> <p>25 working on this, and staff was working on this</p>	<p style="text-align: right;">Page 49</p> <p>1 Q Do you expect it to be more than</p> <p>2 25 hours?</p> <p>3 A Yes.</p> <p>4 Q More than 50 hours?</p> <p>5 A Yes.</p> <p>6 Q More than 100 hours?</p> <p>7 A I would say close to 100 hours, sounds</p> <p>8 about right, but I don't --</p> <p>9 THE COURT REPORTER: I'm sorry. One</p> <p>10 more time.</p> <p>11 THE WITNESS: I don't have an exact</p> <p>12 accounting.</p> <p>13 BY MR. GOLDBERG:</p> <p>14 Q Your -- the retention agreement, which</p> <p>15 we marked as Conti 1, says your hourly rate is \$675.</p> <p>16 Does that sound right to you?</p> <p>17 A Hold on. Let me just look again.</p> <p>18 Q Sure.</p> <p>19 A So, yeah, it does. I think my hourly</p> <p>20 rate has gone up a little bit over time, maybe by</p> <p>21 \$100, but I'm not exactly sure.</p> <p>22 Q And for -- you would invoice your time</p> <p>23 to Greylock, as well?</p> <p>24 A Yes.</p> <p>25 Q What are -- what do Bennett -- what</p>

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<p style="text-align: right;">Page 50</p> <p>1 are Bennett and Sara's backgrounds? Are they 2 Ph.D.s? Are they -- what -- what do they do? 3 A So Bennett and Sarah both have -- are 4 both highly trained quantitative people. I would 5 say Sarah largely assists me on research through 6 identifying documents and specific facts that might 7 be helpful. I would say Bennett largely works on 8 data cleaning, manipulation and analysis. I have 9 not seen either of their CVs, but I have worked very 10 closely with them for a long time. 11 Q When you think about your expert 12 declaration, it's broken up into -- sort of at the 13 beginning -- your calculations of damages kind of 14 appear at the end of the declaration. Did -- did 15 either Bennett or Sarah do more in terms of the 16 calculations of damages? How did the work break up 17 in terms of writing, drafting your report? 18 A Okay. I think you're 19 mischaracterizing my report, number one. 20 So the estimate of damages is found in 21 the front, and then the discussion of how to 22 calculations -- how to calculate the report is kind 23 of in the middle. And then the actual -- actual 24 calculations are summarized at the end. And then 25 there are appendices that provide the details of the</p>	<p style="text-align: right;">Page 52</p> <p>1 but I wrote my report. And they worked at my 2 direction. 3 Q And then did you provide drafts to 4 plaintiff's counsel to obtain comments from them 5 about your report? 6 MR. HONIK: I'm sorry. I didn't hear 7 the question. May I have it back, Jamie? 8 THE COURT REPORTER: Sure. 9 (Whereupon, the question was read back 10 as requested.) 11 MR. HONIK: Thank you. It's a yes or 12 no. 13 THE WITNESS: Yes. 14 BY MR. GOLDBERG: 15 Q Did anyone outside of 16 Greylock McKinnon or plaintiff's counsel provide 17 input to your report? 18 A No. 19 Q Did anyone at Boston University help 20 gather information for your report? 21 A No. 22 MR. GOLDBERG: Can we pull up Tab 52? 23 I'm gonna mark as Tab 52 Defendant's Amended 24 Notice to Videotaped Deposition of Dr. Conti. 25 (Whereupon, Exhibit Conti 2 was marked</p>
<p style="text-align: right;">Page 51</p> <p>1 data and the specific calculations. 2 I wrote my report. 3 Q What do you mean by that? 4 A I mean I wrote my report. 5 Q Okay. You mentioned that there were 6 lots of drafts and back and forth. You wrote it, 7 you shared it with your colleagues at 8 Greylock McKinnon to comment on it? 9 A I think that's a mischaracterization. 10 Q Did your colleagues at 11 Greylock McKinnon not comment on your draft report? 12 A Again, I think that's a 13 mischaracterization. 14 Q Okay. So just tell me. This isn't 15 too much of a mystery. I'm just trying to 16 understand. 17 Did you share your report with your 18 team at Greylock McKinnon so they could provide 19 edits to it and comment to it? 20 A Okay. So I wrote my report, and 21 Greylock -- folks who work at Greylock McKinnon 22 helped me fill in citations where I asked them to 23 provide -- to identify full citations for certain 24 types of facts. They helped me fill in specific 25 numbers. They helped me construct certain exhibits,</p>	<p style="text-align: right;">Page 53</p> <p>1 for Identification.) 2 MR. HONIK: And we're calling that 3 Conti 2? 4 MR. GOLDBERG: And this is going to be 5 marked as Conti 2, yes. 6 BY MR. GOLDBERG: 7 Q Do you recognize this document, 8 Dr. Conti? 9 A Yes. 10 Q Did you receive this document? 11 A Yes. 12 Q And this document, you understand, 13 made certain document requests of you? 14 A Yes. I understand on Exhibit A, 15 Page 3, or actually, Page 2, 3 and 4. 16 Q What did you do to respond to this set 17 of document requests? 18 MR. HONIK: Dr. Conti, I have no 19 objection to the question, but don't reveal 20 discussions with counsel. It's protected by 21 the work product privilege. 22 THE WITNESS: Thank you. 23 So there were 17 requests. They 24 included my current up-to-date resume or CV. 25 That, I worked on with Sarah Stone to get it to</p>

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Page 54	Page 56
<p>1 be updated, and then it was provided to counsel 2 to provide to you. 3 Number 2 was a list of all articles, 4 abstracts, studies, reports, seminar materials, 5 presentations, publications or other writings 6 authored or co-authored by me from 2022 to the 7 present, that relate to the use of data after 8 team members -- the use of pharmaceutical 9 data -- 10 Q Doctor. Doctor, I don't -- 11 A Hold on. 12 Q Hang on. Hang on. Hang on. 13 MR. HONIK: Mr. Goldberg, let her 14 finish, and then you can interject whatever -- 15 MR. GOLDBERG: Hang on a second. It's 16 not -- the answer is not responsive to the 17 question. And also, we really don't need to 18 waste -- just hang on, Doctor. We don't need 19 to waste the time. I'm not asking you to read 20 the request out loud. I'm not asking you to 21 read it. My question was what did you do to 22 respond. 23 MR. HONIK: Excuse me. Excuse me. 24 Seth, respectfully, she is completely 25 responsive to your question. It's within her</p>	<p>1 in specifics. So -- so there's a -- 2 Q What did you -- 3 A Hold on, please let me finish. 4 You requested 17 separate items, so in 5 order to answer your question, I am happy to tell 6 you, for each request, how I answered -- how I 7 gathered documents and provided that information. 8 Q Okay. We don't have to do that. 9 Okay. We'll -- we'll get to it. 10 MR. GOLDBERG: Can we pull up document 11 65, please? 12 BY MR. GOLDBERG: 13 Q Do you recognize the document that's 14 on the screen? 15 A No. 16 MR. GOLDBERG: Marking as Conti 3, the 17 document entitled, "Plaintiffs' Objections and 18 Responses to Defendants' Notice of Videotaped 19 Deposition of Rena Conti, Ph.D." 20 (Whereupon, Exhibit Conti 3 was marked 21 for Identification.) 22 BY MR. GOLDBERG: 23 Q Is this the first time you're seeing 24 this document, Dr. Conti? 25 A Well, let me look through in detail,</p>
Page 55	Page 57
<p>1 province to answer it in whatever way she 2 thinks is appropriate. To frame her response, 3 she is going through each request and 4 identifying what she did. 5 Now, I'd like her to complete her 6 response which you cut off. If you'd like to 7 sharpen your question in some way and perhaps 8 give her an instruction, that's fine. I have 9 no objection. 10 MR. GOLDBERG: That's fine. 11 MR. HONIK: But -- but she was in the 12 middle -- she was in the middle of a response, 13 which was highly responsive, even if it didn't 14 satisfy what you wanted. 15 You can continue, Dr. Conti, and then 16 pause. 17 MR. GOLDBERG: Objection. I'm 18 withdrawing -- I'm withdrawing the question, so 19 there's no reason... 20 MR. HONIK: That's fine. Very good. 21 Thank you. Next question. 22 BY MR. GOLDBERG: 23 Q Did you -- did you collect any 24 documents to respond to this request? 25 A Yes. That's what I'm trying to answer</p>	<p>1 please. I'm on Page 6. I think there are -- 2 Q Yeah, my question was -- 3 A -- 15 pages. You asked me if I had 4 seen this, and I'm saying I'm going to look through. 5 Q We can go off the record while you do 6 that. 7 MR. HONIK: Are you nearly done, 8 Dr. Conti? 9 THE WITNESS: I'm on Page 8 now. If 10 you can just give me a little bit more time. 11 MR. GOLDBERG: Let's go off the 12 record. 13 THE VIDEOGRAPHER: The time is 11:29. 14 We're going off the record. 15 (Whereupon, a short break was taken.) 16 THE VIDEOGRAPHER: The time is 11:30. 17 We're back on the record. 18 BY MR. GOLDBERG: 19 Q Dr. Conti, have you seen this document 20 before, what we've marked as Conti 3? 21 A No, I have not. 22 MR. GOLDBERG: Can you pull up -- the 23 document -- the document that's Tab -- I 24 believe it's Tab 0. Do you have a copy of your 25 report handy? If not, there's one in the</p>

15 (Pages 54 - 57)

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<p style="text-align: right;">Page 58</p> <p>1 binder.</p> <p>2 A I didn't hear you with it.</p> <p>3 THE COURT REPORTER: I didn't hear</p> <p>4 you.</p> <p>5 Q Your report is the first document in</p> <p>6 Binder 1. Do you have -- get that unless you have a</p> <p>7 copy of it handy.</p> <p>8 A I have Tab 1 in front of me.</p> <p>9 Q Okay. Actually, before we get to</p> <p>10 that --</p> <p>11 MR. GOLDBERG: And that can come down,</p> <p>12 sorry about that.</p> <p>13 Could you please pull up</p> <p>14 document 70 -- I'm sorry, not 70, document 67.</p> <p>15 THE VIDEOGRAPHER: This will be</p> <p>16 Exhibit 4?</p> <p>17 MR. GOLDBERG: This will be, yes.</p> <p>18 THE WITNESS: I'm sorry. Did you say</p> <p>19 64?</p> <p>20 MR. HONIK: 67.</p> <p>21 MR. GOLDBERG: Document 67, which we</p> <p>22 are marking as Exhibit Conti 4.</p> <p>23 (Whereupon, Exhibit Conti 4 was marked</p> <p>24 for Identification.)</p> <p>25</p>	<p style="text-align: right;">Page 60</p> <p>1 A Right. I think winter 2020 is when we</p> <p>2 first started having discussions, like I said,</p> <p>3 before the pandemic.</p> <p>4 Q Yeah. Okay. Yeah. I know earlier</p> <p>5 you said February, March, but it looks like it was</p> <p>6 more like January that you got into this matter; is</p> <p>7 that correct?</p> <p>8 A Well, that's what it says here, so</p> <p>9 must be.</p> <p>10 Q And just going through -- at the time,</p> <p>11 it looks like your hourly rate was \$675 an hour if</p> <p>12 we go to that column. And you said that your hourly</p> <p>13 rate is different now?</p> <p>14 A Is that a question?</p> <p>15 Q Well, I'm trying to -- do you know</p> <p>16 what your hourly rate is now? It looks like if you</p> <p>17 go three or four pages in --</p> <p>18 A Yeah.</p> <p>19 Q What is your hourly rate now?</p> <p>20 A I think it's either 750 or 775. I</p> <p>21 think it has changed a little bit over time.</p> <p>22 Q Okay. We'll get there, but it is 775.</p> <p>23 Let's just go down this -- let's just</p> <p>24 go through this so we can get some names here. Who</p> <p>25 is -- after -- so you have four entries for</p>
<p style="text-align: right;">Page 59</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q Do you recognize document -- the</p> <p>3 document we have marked as Conti 4?</p> <p>4 A No.</p> <p>5 Q I'll represent to you that these were</p> <p>6 the invoices of Greylock McKinnon Associates that</p> <p>7 were provided in response to the document request.</p> <p>8 Do you have any reason to disagree with that</p> <p>9 representation?</p> <p>10 A No.</p> <p>11 Q And you can see that this is -- at</p> <p>12 least on the first page, you can see it's an invoice</p> <p>13 submitted to Conlee Whitely and David Stanoch.</p> <p>14 Okay. Do you see that?</p> <p>15 A Yes.</p> <p>16 Q And those are plaintiffs' counsel in</p> <p>17 this case, right?</p> <p>18 A That's my understanding, yes.</p> <p>19 Q I just want to ask you about a few of</p> <p>20 the invoices here, some entries on these, just so we</p> <p>21 can understand. It looks like -- looking at the</p> <p>22 first page, and I do believe these are in</p> <p>23 chronological order. It looks like you first</p> <p>24 started working on this back in January of 2020. Is</p> <p>25 that more or less correct?</p>	<p style="text-align: right;">Page 61</p> <p>1 Dr. Conti in 2020. And who is the next person?</p> <p>2 A Mike Augustejn.</p> <p>3 Q What did Mike do?</p> <p>4 A It says that he discussed --</p> <p>5 Q Okay. What -- what does -- what did</p> <p>6 Mike do on the -- not in this particular entry.</p> <p>7 What did Mike do for the project?</p> <p>8 A Mike is also an expert on data and --</p> <p>9 THE COURT REPORTER: And what?</p> <p>10 THE WITNESS: Data, acquisition in</p> <p>11 cleaning, in manipulation, in analysis. And so</p> <p>12 I would expect that he would have worked on</p> <p>13 this in that capacity.</p> <p>14 BY MR. GOLDBERG:</p> <p>15 Q Going to the next person,</p> <p>16 Bennett Erickson?</p> <p>17 A Correct.</p> <p>18 Q What did Bennett Erickson do,</p> <p>19 generally, for the project?</p> <p>20 MR. HONIK: Objection, asked and</p> <p>21 answered.</p> <p>22 THE WITNESS: Right. So I've already</p> <p>23 answered --</p> <p>24 MR. GOLDBERG: I'm sorry.</p> <p>25 THE WITNESS: So --</p>

16 (Pages 58 - 61)

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<p style="text-align: right;">Page 62</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q I can withdraw the question. I'm</p> <p>3 sorry. You did talk about Bennett before.</p> <p>4 The next person is Brian Hebert. What</p> <p>5 did Brian do for the project, generally?</p> <p>6 A So it looks here that he billed time</p> <p>7 for import checking of manufacturing data.</p> <p>8 Q Do you know what -- what manufacturing</p> <p>9 data he looked at?</p> <p>10 A I don't.</p> <p>11 Q Do you know what -- what is meant by</p> <p>12 the phrase "manufacturing data"?</p> <p>13 A I'm assuming it was data that was</p> <p>14 related to the sale of these products.</p> <p>15 Q That's pretty broad. Do you -- is</p> <p>16 there any particular data that you think he looked</p> <p>17 at related to the sale of the products?</p> <p>18 A I don't know.</p> <p>19 Q If you go on into 2021, now you've got</p> <p>20 Sarah Honan added to the invoices. Who is</p> <p>21 Sarah Honan? Is that the Sarah we mentioned</p> <p>22 earlier? No, that was Sarah Stone.</p> <p>23 A Right, Sarah Stone. So Sarah Stone</p> <p>24 and Bennett Erickson are the people that I have been</p> <p>25 working with at GMA on this matter. There are a</p>	<p style="text-align: right;">Page 64</p> <p>1 What -- what was that?</p> <p>2 A I don't know.</p> <p>3 Q You don't know what he meant by "cGMP</p> <p>4 market share analysis"?</p> <p>5 A I'm assuming it has something to do</p> <p>6 with -- there are multiple manufacturers of these</p> <p>7 products at issue in this matter. But I don't know</p> <p>8 what he specifically meant on this date.</p> <p>9 Q Do you know if Bennett's cGMP market</p> <p>10 share analyses were produced in this case?</p> <p>11 A I'm sorry, what do you mean by</p> <p>12 "produced"?</p> <p>13 Q Provided to plaintiffs' counsel for</p> <p>14 production in this case.</p> <p>15 A You mean did Bennett turn those</p> <p>16 documents over to you?</p> <p>17 Q Well, did Greylock McKinnon or Bennett</p> <p>18 provide them to plaintiffs' counsel to produce in</p> <p>19 this case?</p> <p>20 A Well, I'm assuming -- so I -- I mean,</p> <p>21 the short answer is I don't know. The longer answer</p> <p>22 is by definition, my report contains the sales of</p> <p>23 these products across different manufacturers over</p> <p>24 time. And so I'm assuming that it's related to what</p> <p>25 Bennett states here, and those -- all of that back</p>
<p style="text-align: right;">Page 63</p> <p>1 handful of other people that generally support</p> <p>2 Bennett and Sarah that I don't know as well. So</p> <p>3 Sarah Honan is -- is one of those people.</p> <p>4 Q Do you know -- can you describe,</p> <p>5 generally, what she did for the project?</p> <p>6 A It says here "Imported IQVIA data."</p> <p>7 Q If you -- on the third page of the</p> <p>8 document, assuming you have double-sided copies,</p> <p>9 it's -- it's invoice 21158.</p> <p>10 A Yes. That's not what's on the screen,</p> <p>11 but I see -- I am on that.</p> <p>12 Q Okay. The first entry for Bennett</p> <p>13 says, "Work on valsartan cGMP market share</p> <p>14 analysis."</p> <p>15 What -- do you know what that means?</p> <p>16 A I'm sorry, I'm a little confused,</p> <p>17 because what's on the screen is not -- I don't think</p> <p>18 what we're talking about, so can we just make sure</p> <p>19 we're on the same page?</p> <p>20 So invoice 21158, is that what we're</p> <p>21 talking about right now?</p> <p>22 Q Right.</p> <p>23 A Okay. Good. So --</p> <p>24 Q The question is, Bennett says he</p> <p>25 worked on valsartan cGMP market share analysis.</p>	<p style="text-align: right;">Page 65</p> <p>1 up and -- have been produced. They are part of my</p> <p>2 report.</p> <p>3 Q Did you rely on a market share</p> <p>4 analysis in reaching your report -- in reaching your</p> <p>5 opinions?</p> <p>6 A Again, by definition, the at-issue</p> <p>7 products are valsartan drugs made by different</p> <p>8 manufacturers. My report had to identify those</p> <p>9 manufacturers in national data and then apportion</p> <p>10 sales of those products across different</p> <p>11 manufacturers.</p> <p>12 If you go further down on the fourth</p> <p>13 line, Bennett says, "Work on review of repackager</p> <p>14 NDCs. Create comparison of FDA-recalled" --</p> <p>15 COURT REPORTER: I'm sorry, Doctor.</p> <p>16 Bennett says, "Work on review of..."</p> <p>17 THE WITNESS: "Repackager NDCs.</p> <p>18 Create comparison of FDA-recalled NDCs to IQVIA</p> <p>19 NDCs."</p> <p>20 I think that -- so -- so there is an</p> <p>21 FDA list of recalled valsartan products, and --</p> <p>22 that identifies products by NDC code in the</p> <p>23 IQVIA data. I can identify products by NDC</p> <p>24 code, but products are very commonly repackaged</p> <p>25 and relabeled by private label -- by private</p>

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<p style="text-align: right;">Page 66</p> <p>1 label distributors and even retailers such as 2 CVS or Costco. 3 And so in order to go from the NDC 4 list produced by the -- by the FDA to Xponent 5 was actually sold into the U.S. market, there 6 is -- there is a job that needs to get done. 7 Because repackagers or relabelers will change 8 the NDC code by definition. 9 And so there was work that was done to 10 match NDC codes or drugs at issue in this 11 matter with the national sales that we had on 12 these products. All of that was produced in my 13 report. 14 BY MR. GOLDBERG: 15 Q Let's just start at the beginning of 16 this. And if you go back to the first page of this 17 document, do you see it says, for you, Dr. Conti -- 18 THE COURT REPORTER: I'm sorry, Seth. 19 Can you start that again? 20 BY MR. GOLDBERG: 21 Q It looks like you invoiced two hours, 22 2.6 hours; is that correct? 23 A Yes, I see that here. 24 Q And if you go along with me to the 25 next invoice, there's -- there's no entry for</p>	<p style="text-align: right;">Page 68</p> <p>1 MR. HONIK: Thank you. 2 MR. GOLDBERG: Sure. 3 MR. HONIK: I see it now. Thank you. 4 BY MR. GOLDBERG: 5 Q And then if we go to -- 6 A It's two pages, actually. It's two 7 pages. 8 Q Right. And there's no entry for 9 Dr. Conti on that invoice, correct? 10 A Correct. 11 Q And then the next invoice is 21158. 12 Do you see that? 13 A Yes. 14 Q And there's no invoice for Dr. Conti 15 there? There's no time invoiced for Dr. Conti in 16 that invoice, correct? 17 A Correct, but there is mention of me 18 participating in calls with the attorney. 19 Q So you participated in that call on 20 May 24th, 2021, right? 21 A Yes. 22 Q Let's turn to the next invoice, which 23 is 21617. There we see Dr. Conti, you billed 24 12.75 hours, right? Correct? 25 A I'm just -- I didn't -- I didn't</p>
<p style="text-align: right;">Page 67</p> <p>1 Dr. Conti; am I correct? 2 A You mean -- again, I don't know -- 3 Q Invoice -- 4 COURT REPORTER: All right. I 5 cannot -- I can't take both of you down at the 6 same time. And you're both interrupting each 7 other, and so you're not giving me a chance to 8 do my job. 9 MR. GOLDBERG: Okay. Let's not worry 10 about the screen since you have the binder in 11 front of you, and that was the purpose of 12 giving you the document in hard copy. So can 13 you -- and the tech can follow along if the 14 tech can follow along. 15 BY MR. GOLDBERG: 16 Q Right now I'm looking at 17 Invoice 21024, which is in your binder. Do you see 18 that. 19 A Yes. 20 Q Okay. And there's not an entry for 21 Dr. Conti in there, correct? 22 MR. HONIK: Seth, I think for the 23 benefit of myself and all other counsel, can 24 the tech bring up the specific document? 25 MR. GOLDBERG: Sure.</p>	<p style="text-align: right;">Page 69</p> <p>1 prepare this invoice, so I'm just looking through -- 2 Q Sure. 3 A -- what is actually billed. That's 4 correct. 5 Q And that invoice takes us through 6 12-29-21. It's the last date anyone billed time on 7 that invoice. Do you see that? 8 A Well, it's the last time that some of 9 the staff billed time on the invoice. I can see 10 that. 11 Q Based on my review of these invoices, 12 before December 29th, 2021, you billed, in total, 13 approximately 15 hours for your work in this matter; 14 is that a fair representation? 15 MR. HONIK: Object to form. 16 THE WITNESS: Well, again, I didn't 17 produce these documents, so I just simply 18 billed for the time that's listed here. But if 19 there's a different process for what I submit 20 and what GMA does in what is listed here if 21 there is time, I'm happy -- that I billed, I'm 22 happy to total it up. I haven't done that. 23 It looks like, in the first invoice, 24 there's about two-and-a-half hours. 25 COURT REPORTER: There is -- there's</p>

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<p style="text-align: right;">Page 70</p> <p>1 what?</p> <p>2 THE WITNESS: About two-and-a-half</p> <p>3 hours.</p> <p>4 In the last invoice there's about 12,</p> <p>5 almost 13 hours. So I think that's fair. So</p> <p>6 there's approximately 15 to 16 hours that I</p> <p>7 billed for my time on these invoices.</p> <p>8 BY MR. GOLDBERG:</p> <p>9 Q Are there other Greylock McKinnon</p> <p>10 invoices that haven't been produced?</p> <p>11 A So I am woefully behind in my time on</p> <p>12 this matter. I have a list of the time that I have</p> <p>13 worked on this, but it has not been completely</p> <p>14 submitted to Greylock McKinnon or to the attorneys.</p> <p>15 Q But you were asked --</p> <p>16 Greylock McKinnon was asked to produce your invoices</p> <p>17 in this case, and you didn't comply with that</p> <p>18 request?</p> <p>19 MR. HONIK: Object to the form.</p> <p>20 THE WITNESS: Of course I did.</p> <p>21 BY MR. GOLDBERG:</p> <p>22 Q Well, why don't we have that time and</p> <p>23 your invoices for that?</p> <p>24 A You mean -- you mean all the invoices?</p> <p>25 Q Yeah.</p>	<p style="text-align: right;">Page 72</p> <p>1 also teaching intensely during that time. I have</p> <p>2 actually been teaching intensely since July. And so</p> <p>3 I have been actively working on this case, but I</p> <p>4 have not submitted my time because I frankly did not</p> <p>5 have the time to do it.</p> <p>6 Q Well, let's look at invoice 21617.</p> <p>7 That's the last invoice in the -- in the packet.</p> <p>8 That's your 2021 time. And --</p> <p>9 A I'm sorry. I'm sorry. I'm not -- I'm</p> <p>10 not following you. Where are you?</p> <p>11 Q It's up on the screen, invoice 21617.</p> <p>12 It's the last invoice in the packet.</p> <p>13 A I can see that.</p> <p>14 Q So you billed an hour in May of 2021,</p> <p>15 correct? You billed an hour in September 2021,</p> <p>16 correct? And -- am I correct?</p> <p>17 A I can see that there.</p> <p>18 Q And you billed 10.75 hours in</p> <p>19 October 2021, correct?</p> <p>20 A Correct.</p> <p>21 Q How much time do you expect to bill</p> <p>22 plaintiffs for 2021 in addition to these</p> <p>23 12.75 hours?</p> <p>24 A So I have a preliminary listing of my</p> <p>25 time, and it amounts to approximately 60 hours.</p>
<p style="text-align: right;">Page 71</p> <p>1 A Because I'm really busy, frankly. I'm</p> <p>2 teaching intensely. I've been doing a lot of other</p> <p>3 work to support government activity. And I have a</p> <p>4 very sick mother that I am managing her time and</p> <p>5 also taking care of my kid. So I've been very, very</p> <p>6 busy over the past two months and --</p> <p>7 Q Well, I'm not -- I'm not --</p> <p>8 MR. HONIK: Don't interrupt her,</p> <p>9 please.</p> <p>10 THE WITNESS: So I have been really,</p> <p>11 really busy, and so my time is not complete.</p> <p>12 BY MR. GOLDBERG:</p> <p>13 Q I'm not concerned about your time in</p> <p>14 2022. You --</p> <p>15 A I'm saying that my time in 2021, I</p> <p>16 spent the majority of 2021 dealing with a very sick</p> <p>17 mother, traveling in three separate cities and</p> <p>18 taking care of my child, in addition to myself, in</p> <p>19 addition to very intense teaching and other</p> <p>20 activities. I am behind in my time.</p> <p>21 Q Were you able to put your time in for</p> <p>22 some invoices, but not others; is that what you're</p> <p>23 saying?</p> <p>24 A What I'm saying is my mother became</p> <p>25 very sick last summer, and so my time -- and I was</p>	<p style="text-align: right;">Page 73</p> <p>1 Q And that's for 2021?</p> <p>2 A Yes. Oh, 2021 and 2022.</p> <p>3 Q And how much of that time is 2021</p> <p>4 versus 2022?</p> <p>5 A I would say the majority.</p> <p>6 Q Is 2021?</p> <p>7 A Correct.</p> <p>8 Q How much time have you spent on this</p> <p>9 matter -- excuse me -- in 2022?</p> <p>10 A In preparing for the deposition and</p> <p>11 doing a handful of other things, maybe about</p> <p>12 20 hours or so. I don't have a specific accounting</p> <p>13 yet. Again, I've been going back and forth between</p> <p>14 Boston, New York, Philadelphia and Chicago, because</p> <p>15 my mother is really sick, for every single week</p> <p>16 since the new year.</p> <p>17 Q Do you think you'd be able to provide</p> <p>18 that preliminary list to your counsel so that we can</p> <p>19 see it?</p> <p>20 A Sure. I mean, my -- my plan is to --</p> <p>21 to finish it. I don't like to submit bills, and I</p> <p>22 don't -- I don't like to submit bills that I don't</p> <p>23 feel -- that aren't triple checked, and so I have a</p> <p>24 process for doing that.</p> <p>25 MR. GOLDBERG: Why don't we go off the</p>

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<p style="text-align: right;">Page 74</p> <p>1 record and take a five-minute break just to 2 give everybody a minute? 3 MR. HONIK: Why don't we call it 4 10 minutes and come back at 10:07. Okay? 5 MR. GOLDBERG: Sounds good. 6 THE VIDEOGRAPHER: The time is 11:57. 7 This ends Media Unit Number 1. 8 (Whereupon, a short break was taken.) 9 THE VIDEOGRAPHER: The time is 12:11. 10 This begins Media Number 2, and back on the 11 record. 12 BY MR. GOLDBERG: 13 Q Dr. Conti, if you could pull and put 14 in front of you your report -- or your declaration, 15 which we marked as -- which we are going to mark as 16 Conti 5. 17 (Whereupon, Exhibit Conti 5 was marked 18 for Identification.) 19 BY MR. GOLDBERG: 20 Q And I'd like to start at the beginning 21 of your report. 22 A Just give me a second to get it. 23 Q Okay. Let's start at the beginning of 24 your report. I'm going to ask you questions about 25 it in different places, but I'd like to start just</p>	<p style="text-align: right;">Page 76</p> <p>1 that question. 2 Going to the next paragraph, you say, 3 "I have been asked by plaintiffs' counsel to assume 4 that the at-issue valsartan products manufactured 5 and sold by the defendants" -- and I'm gonna go now 6 to the bottom -- "were recalled" -- "that were 7 recalled in 2018 and 2019 were adulterated and 8 misbranded." 9 Do you see that? 10 A Yes. 11 Q What do you mean by "at-issue 12 valsartan products"? 13 A The valsartan products that were 14 listed in Footnote 3 and Footnote 4. 15 Q When you use the phrase "at-issue 16 valsartan products," are you limiting that to 17 valsartan products that contained NDMA or NDEA? 18 A No. 19 COURT REPORTER: I'm sorry? 20 THE WITNESS: No. 21 MR. GOLDBERG: Can we go off the 22 record for one second? 23 THE VIDEOGRAPHER: The time is 12:16. 24 We're going off the record. 25 (Whereupon, a discussion was held off</p>
<p style="text-align: right;">Page 75</p> <p>1 at Paragraph 1. 2 You said you were retained to provide 3 opinions and calculations regarding the -- the 4 injury and damages incurred by classes of consumers 5 and end-payers in this matter. 6 By "this matter," you're referring to 7 the amended economic class action complaint, which 8 is at Footnote 1, correct? 9 A Yes. 10 Q I'm just going to remind you to speak 11 up a little bit, or maybe the microphone needs to be 12 turned up. 13 And by "injury in this matter" -- you 14 use the phrase "injury" -- you're -- you're talking 15 about an economic injury of this matter, correct? 16 A Correct. 17 Q And your damages -- you're not 18 providing opinions on liability, you're providing 19 opinions on damages, right? 20 MR. HONIK: Object to form. 21 THE WITNESS: I'm providing opinions 22 on economic injury and damages. 23 BY MR. GOLDBERG: 24 Q You're not -- you're not -- you 25 haven't reached an opinion as to -- well, strike</p>	<p style="text-align: right;">Page 77</p> <p>1 the record.) 2 THE VIDEOGRAPHER: The time is 12:18. 3 We're back on the record. 4 BY MR. GOLDBERG: 5 Q So when you're using the phrase 6 "at-issue valsartan products" in Paragraph 2 of your 7 declaration and throughout your declaration, 8 you're -- you're including valsartan products that 9 may not have contained NDMA or NDEA? 10 MR. HONIK: Object to form, asked and 11 answered. 12 THE WITNESS: When I am referring to 13 "at-issue valsartan products," they are the 14 ones listed in Footnote 2 and Footnote -- I'm 15 sorry -- Footnote 3 and Footnote 4 of my 16 report. 17 BY MR. GOLDBERG: 18 Q Footnote 3 and Footnote 4 refer to 19 recalled valsartan products, correct? 20 MR. HONIK: Object to form. 21 THE WITNESS: No, not solely. That's 22 a mischaracterization. So Footnote 3 and 23 Footnote 4 define at-issue valsartan products. 24 And they include products manufactured by -- 25 I'm going to say this, and it's -- I'm going to</p>

20 (Pages 74 - 77)

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Page 78	Page 80
<p>1 butcher the name -- Zhejiang Huahai, Teva, 2 Hetero, Torrent, Mylan and Aurobindo. And it 3 includes the valsartan products marketed under 4 Diovan name and their generic equivalent and 5 then marketed under the Exforge name and their 6 generic equivalent during the time period 7 2020 -- 2012 through 2018. 8 BY MR. GOLDBERG: 9 Q So you are including in at-issue 10 valsartan products all valsartan manufactured by 11 those defendants between 2012 and 2018? 12 A Correct. 13 Q That paragraph at the end talks 14 about -- it says that you -- you were asked to 15 assume that those products were adulterated and 16 misbranded. On what basis do you -- 17 A I'm sorry. I'm sorry. I don't 18 know -- what -- what do you mean by "at the end"? 19 Q Okay. If you look at -- if you look 20 at the paragraph, it says, "I have been asked" -- 21 A Paragraph 2, okay. 22 Q You were asked to assume that those 23 products were adulterated and misbranded, correct? 24 A Correct. 25 Q On what basis were you asked to make</p>	<p>1 MR. GOLDBERG: What you understand -- 2 MR. HONIK: Excuse me. Excuse me. 3 MR. GOLDBERG: Counsel, don't 4 interrupt. Don't interrupt. 5 MR. HONIK: I'm going to protect this 6 record in every single way that I want to. And 7 as a courtesy to Ms. Moskowitz, I simply heard 8 a noncontroversial three words and offered them 9 to her to move things along. Thank you. 10 MR. GOLDBERG: Counsel, what do you 11 understand to be the -- the adulteration that 12 you assumed? 13 MR. HONIK: I'm not -- I'm not here to 14 answer your questions. If it's directed -- 15 MR. GOLDBERG: I'm sorry. I'm sorry, 16 Dr. Conti. 17 BY MR. GOLDBERG: 18 Q I'd like to -- I'd like you to explain 19 what you under- -- what you assumed. 20 A So, again, the assumption of 21 adulteration and misbranding is detailed in the 22 complaint and cited in my Paragraph 1 and 23 Paragraph 2 in Footnotes 1, 2, 3 and 4. 24 Q It's fair to say, since you assume 25 those facts that are in that complaint, you didn't</p>
Page 79	Page 81
<p>1 that assumption? 2 A I'm sorry. I don't understand the 3 question. 4 Q What were the -- what was the basis 5 for the adulteration that you were asked to assume? 6 A My understanding is, that basis is 7 outlined in the complaint, which I reference in the 8 first paragraph of my report and also Footnote 1. 9 Q Was there any particular aspect of 10 these drugs that made them -- that you were asked to 11 assume made them adulterated? 12 A Again, the basis of adulteration and 13 misbranding is detailed in the complaint. And the 14 definition of "adulterated" and "misbranded" is also 15 outlined in the complaint, and is also outlined in 16 my report in later paragraphs. 17 COURT REPORTER: Is also outlined in 18 my report... 19 MR. HONIK: In later paragraphs, she 20 said. 21 COURT REPORTER: Thank you. 22 MR. GOLDBERG: Counsel, Counsel, 23 there's no need for you to testify. 24 MR. HONIK: I'm not testifying. It's 25 just that I heard her --</p>	<p>1 reach any independent determination about whether 2 there was an adulteration, correct? 3 A Again, I was asked to assume certain 4 facts about the adulteration and misbranding of 5 valsartan products at issue in this matter. 6 Q So the answer to my question is yes, 7 you didn't independently conclude that there was an 8 adulterated drug? 9 MR. HONIK: Object to form. 10 BY MR. GOLDBERG: 11 Q You were asked to make that 12 assumption? 13 MR. HONIK: Object to the form. 14 BY MR. GOLDBERG: 15 Q Correct? 16 A I was asked to make that assumption, 17 correct, as outlined in the complaint and in the 18 footnotes listed here. 19 Q If you go on to Paragraph 4 of your 20 complaint -- of your report, sorry -- 21 A That's okay. 22 Q The first few lines is where I'm 23 looking. It says, "The adulteration derives from 24 the defendant manufacturers' allowance of chronic 25 and pervasive deficiencies in the manufacturing of</p>

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<p style="text-align: right;">Page 82</p> <p>1 at-issue valsartan products."</p> <p>2 What did you mean by "chronic and</p> <p>3 pervasive deficiencies"?</p> <p>4 A My understanding is that there were --</p> <p>5 there are systematic failures of cGMP in the</p> <p>6 manufacturing of the at-issue valsartan products by</p> <p>7 the manufacturers.</p> <p>8 Q What are those systematic failures</p> <p>9 that you're referring to?</p> <p>10 MR. HONIK: Objection, asked and</p> <p>11 answered.</p> <p>12 THE WITNESS: There -- there is -- my</p> <p>13 understanding is that there are -- there are</p> <p>14 many of them, and those are outlined in the</p> <p>15 complaint and also supporting FDA documents of</p> <p>16 cGMP violations that the manufacturers were</p> <p>17 cited for.</p> <p>18 BY MR. GOLDBERG:</p> <p>19 Q You wrote your report, correct?</p> <p>20 A I did.</p> <p>21 Q Okay. So when you wrote "chronic and</p> <p>22 pervasive deficiencies," what were you -- what were</p> <p>23 you documenting? What chronic and pervasive --</p> <p>24 MR. HONIK: Objection, asked and</p> <p>25 answered.</p>	<p style="text-align: right;">Page 84</p> <p>1 looked at and relied upon in reaching your opinions,</p> <p>2 that's listed here; is that correct?</p> <p>3 A I don't think that's accurate, because</p> <p>4 again, I am in -- as an expert in the regulation of</p> <p>5 the pharmaceutical industry, and in many other</p> <p>6 contexts, I have spent a lot of time thinking about</p> <p>7 the -- the requirements of manufacturers, that they</p> <p>8 need to meet, in order to meet cGMP, and also</p> <p>9 violation of cGMP. I have also spent a lot of time</p> <p>10 thinking about and thinking on adulteration and</p> <p>11 misbranding of products, generally, in this</p> <p>12 industry.</p> <p>13 So again, it's -- the materials relied</p> <p>14 upon or the ones listed here are the most germane to</p> <p>15 this specific matter. But my experience is also</p> <p>16 germane. That's in Attachment A.</p> <p>17 Q Okay. So my question was, the</p> <p>18 documents that you relied upon to reach your</p> <p>19 opinions in this matter, leaving aside your</p> <p>20 experience and your general knowledge, but the</p> <p>21 specific documents that you relied upon to reach</p> <p>22 your opinions in this matter, are set forth in</p> <p>23 Attachment B, correct?</p> <p>24 MR. HONIK: Object to the form, asked</p> <p>25 and answered.</p>
<p style="text-align: right;">Page 83</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q What chronic and pervasive</p> <p>3 deficiencies were you referring to?</p> <p>4 MR. HONIK: Object to form, asked and</p> <p>5 answered.</p> <p>6 THE WITNESS: The ones that are</p> <p>7 referred to in the complaint at issue in this</p> <p>8 matter.</p> <p>9 BY MR. GOLDBERG:</p> <p>10 Q Any others?</p> <p>11 A No.</p> <p>12 Q Could you -- I -- I should have done</p> <p>13 this before, but if you could look at Attachment B</p> <p>14 to your report, which is up on the screen, as well,</p> <p>15 this -- this -- this attachment says, "Materials</p> <p>16 relied upon." Did you prepare this attachment?</p> <p>17 A My staff, under my direction, prepared</p> <p>18 this document.</p> <p>19 Q And is it fair to say that these were</p> <p>20 the materials you relied upon in reaching your</p> <p>21 opinions?</p> <p>22 A In addition to my expertise and my</p> <p>23 experience in this matter -- or my experience in</p> <p>24 this industry.</p> <p>25 Q So there was a document that you</p>	<p style="text-align: right;">Page 85</p> <p>1 THE WITNESS: I don't -- I mean,</p> <p>2 again, I don't quite understand the distinction</p> <p>3 you're making. So again, my expertise and</p> <p>4 experience in the regulation of this industry</p> <p>5 informs everything I do, including the opinions</p> <p>6 that -- and the calculations that I performed</p> <p>7 in this matter.</p> <p>8 Attachment A provides my CV, which has</p> <p>9 an extensive list of things that I have</p> <p>10 published on this industry. But Attachment B</p> <p>11 is enumerating the materials that I</p> <p>12 specifically relied on in this matter. But I</p> <p>13 don't see how I could distinguish between my</p> <p>14 experience generally in this industry and the</p> <p>15 materials that I relied on.</p> <p>16 BY MR. GOLDBERG:</p> <p>17 Q Well, you just -- you did, because</p> <p>18 this document says, "Materials Relied Upon." So</p> <p>19 you're making a distinction between your CV and the</p> <p>20 materials that you relied upon, right?</p> <p>21 A No, you are. No, you are. What I'm</p> <p>22 saying is my experience informs the materials that I</p> <p>23 relied upon, by definition. I mean, I -- I know a</p> <p>24 lot about cGMP and the regulation of the</p> <p>25 products --</p>

22 (Pages 82 - 85)

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<p style="text-align: right;">Page 86</p> <p>1 Q Did you --</p> <p>2 A Hold on, please, if I can finish.</p> <p>3 I know a lot about the regulation of</p> <p>4 these products in the U.S. market. But it's based</p> <p>5 upon my experience working on many different aspects</p> <p>6 of this market. And it's many different products.</p> <p>7 That informs the documents that were selected and</p> <p>8 thought about specifically or cited specifically in</p> <p>9 my report.</p> <p>10 Q Did you review any deposition</p> <p>11 testimony in reaching your opinions?</p> <p>12 A No.</p> <p>13 Q Did you --</p> <p>14 A As I -- hold on. As I understand</p> <p>15 it --</p> <p>16 Q No. No. No. You answered the</p> <p>17 question.</p> <p>18 A No. No. No. I didn't answer.</p> <p>19 MR. HONIK: She has not finished her</p> <p>20 response. Do not interrupt the witness.</p> <p>21 THE WITNESS: So, as I understand it,</p> <p>22 the reports that were produced that mention my</p> <p>23 report, none of those people had been deposed</p> <p>24 yet. So I would have liked to have seen their</p> <p>25 depositions, because some of it -- what they</p>	<p style="text-align: right;">Page 88</p> <p>1 in this case?</p> <p>2 A My understanding, again, of the</p> <p>3 defendant experts in this case is that they have</p> <p>4 not -- they've produced reports, but they have not</p> <p>5 been deposed yet. So I don't see how I could read a</p> <p>6 deposition if it hasn't occurred yet.</p> <p>7 Q If you go back in your report to</p> <p>8 Paragraph 4 --</p> <p>9 A I'm sorry. I didn't hear you. I</p> <p>10 can't hear you.</p> <p>11 THE COURT REPORTER: Seth, I can't</p> <p>12 hear you either.</p> <p>13 MR. GOLDBERG: Sorry about that.</p> <p>14 BY MR. GOLDBERG:</p> <p>15 Q The third line refers to "a failure by</p> <p>16 the defendant manufacturers to implement quality</p> <p>17 assurance practices."</p> <p>18 Do you have any specific understanding</p> <p>19 of what those quality assurance practices were?</p> <p>20 MR. HONIK: Objection, asked and</p> <p>21 answered.</p> <p>22 THE WITNESS: So manufacturers who are</p> <p>23 legally allowed to supply products to the</p> <p>24 pharmaceutical U.S. chains are required to</p> <p>25 attest to a very significant number of quality</p>
<p style="text-align: right;">Page 87</p> <p>1 say in the reports is confusing. But I have</p> <p>2 not -- my understanding is they have not been</p> <p>3 deposed yet.</p> <p>4 BY MR. GOLDBERG:</p> <p>5 Q Did you review any depositions of any</p> <p>6 witnesses in reaching your opinions in this case?</p> <p>7 A No. I mean, some of -- like I said,</p> <p>8 the ones that I would have liked to have reviewed, I</p> <p>9 wasn't able to because they haven't been deposed</p> <p>10 yet.</p> <p>11 Q So you haven't read a deposition of a</p> <p>12 plaintiff in this case?</p> <p>13 A No.</p> <p>14 Q Or a plaintiff --</p> <p>15 A I understand that the depositions</p> <p>16 haven't been done of the economic experts.</p> <p>17 Q I'm asking you about the plaintiffs.</p> <p>18 I'm not asking you about experts. You haven't read</p> <p>19 a deposition of a plaintiff in this case, correct?</p> <p>20 A I have not.</p> <p>21 Q You haven't read the deposition of a</p> <p>22 class representative in this case?</p> <p>23 A I have not.</p> <p>24 Q And you haven't read -- read the</p> <p>25 deposition of any defendant witnesses or employees</p>	<p style="text-align: right;">Page 89</p> <p>1 assurance practices, which include but are not</p> <p>2 limited to the risk, assessment and mitigation</p> <p>3 of their -- of their product from end to end.</p> <p>4 And there's also attestation of the practices</p> <p>5 that the firms are required to provide to</p> <p>6 the --</p> <p>7 THE COURT REPORTER: To the -- I'm</p> <p>8 sorry. To the what?</p> <p>9 THE WITNESS: Are required to provide</p> <p>10 to the U.S. Food and Drug Administration, upon</p> <p>11 their initial application to get a license to</p> <p>12 sell these products to the U.S. market, but</p> <p>13 also over time. Yes, that's what I mean by</p> <p>14 "quality assurance practices."</p> <p>15 BY MR. GOLDBERG:</p> <p>16 Q Do you have any particular instances</p> <p>17 of quality assurance practices or the failure to</p> <p>18 implement quality assurance practices as to any of</p> <p>19 the defendants in this case?</p> <p>20 MR. HONIK: Object to form and asked</p> <p>21 and answered.</p> <p>22 THE WITNESS: Yes. They are detailed</p> <p>23 in the complaint, and they are also detailed in</p> <p>24 the FDA documents that are listed in --</p> <p>25 detailing for each one of the defendants on the</p>

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<p style="text-align: right;">Page 90</p> <p>1 systematic --</p> <p>2 THE COURT REPORTER: On the</p> <p>3 systematic --</p> <p>4 THE WITNESS: And pervasive quality</p> <p>5 assurance.</p> <p>6 COURT REPORTER: Excuse me, Counsel.</p> <p>7 One second. Let me see if I can turn my volume</p> <p>8 up.</p> <p>9 THE VIDEOGRAPHER: Mr. Goldberg, I</p> <p>10 think the -- the paper shuffling may be</p> <p>11 distracting a little bit.</p> <p>12 THE WITNESS: Correct. It's very hard</p> <p>13 to hear.</p> <p>14 COURT REPORTER: Okay. I put my</p> <p>15 volume up.</p> <p>16 BY MR. GOLDBERG:</p> <p>17 Q Did you review any document that --</p> <p>18 that detailed for you a failure to implement quality</p> <p>19 assurance practices by the defendant manufacturers?</p> <p>20 MR. HONIK: Object to form, asked and</p> <p>21 answered.</p> <p>22 THE WITNESS: Yes. The complaint</p> <p>23 details systematic and pervasive deficiency</p> <p>24 in -- in the cGMP. And then there are FDA</p> <p>25 documents that are supportive of that for each</p>	<p style="text-align: right;">Page 92</p> <p>1 THE VIDEOGRAPHER: The time is 12:42.</p> <p>2 We're back on the record.</p> <p>3 BY MR. GOLDBERG:</p> <p>4 Q I want you to listen to the questions</p> <p>5 I'm going to ask. I just want you answer the</p> <p>6 questions I'm going to ask. Okay?</p> <p>7 The binder that -- the binder that you</p> <p>8 have in front of you now --</p> <p>9 A Correct.</p> <p>10 Q -- you did not provide that binder to</p> <p>11 your counsel before today, correct?</p> <p>12 MR. HONIK: Object to the form of the</p> <p>13 question.</p> <p>14 THE COURT REPORTER: What was your</p> <p>15 answer?</p> <p>16 THE WITNESS: I mean, I did not -- I,</p> <p>17 me, provide it. It's the complaint and the</p> <p>18 backup and some of the documents listed in the</p> <p>19 complaint. The complaint is listed in my</p> <p>20 Attachment B, and the documents that are</p> <p>21 related specifically to inspection reports,</p> <p>22 FDA, failure notices to the -- to each of the</p> <p>23 manufacturers are just the complaint. They're</p> <p>24 just the backup to the complaint.</p> <p>25</p>
<p style="text-align: right;">Page 91</p> <p>1 of the defendant manufacturers that details</p> <p>2 many different deficiencies in cGMP.</p> <p>3 BY MR. GOLDBERG:</p> <p>4 Q Which FDA documents --</p> <p>5 A Hold on. In the manufacturing of</p> <p>6 these products.</p> <p>7 Q Which FDA documents are you referring</p> <p>8 to?</p> <p>9 A Hold on a second. We were just</p> <p>10 looking at the materials relied upon. I think it's</p> <p>11 in Attachment B.</p> <p>12 So there's the complaint and</p> <p>13 then -- and -- I don't see it assessed here, but I</p> <p>14 have a binder of FDA documents that are specific to</p> <p>15 each one of the manufacturers that I have reviewed</p> <p>16 that are related to the at-issue products here.</p> <p>17 Q What binder are you referring to?</p> <p>18 A I'm happy to get it if you can just</p> <p>19 give me a second.</p> <p>20 MR. GOLDBERG: Let's go off the</p> <p>21 record.</p> <p>22 THE VIDEOGRAPHER: The time is 12:42.</p> <p>23 We're going off the record.</p> <p>24 (Whereupon, a discussion was held off</p> <p>25 the record.)</p>	<p style="text-align: right;">Page 93</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q Okay. I understand.</p> <p>3 So you're saying you looked at the</p> <p>4 complaint and the exhibits to the complaint?</p> <p>5 A Correct.</p> <p>6 Q That's what is in that binder?</p> <p>7 A Yes. And specifically, I reviewed</p> <p>8 the -- the backup material that the complaint</p> <p>9 references related to the systematic and</p> <p>10 persuasive [sic] failures of cGMP for each of the</p> <p>11 defendants.</p> <p>12 So I'm gonna say this incorrectly</p> <p>13 again, Zhejiang Huahai --</p> <p>14 Q You don't have to -- you don't have to</p> <p>15 name the defendants. We know who they are.</p> <p>16 A Okay. No, I'm just telling you -- I'm</p> <p>17 saying to you, not the defendants, but for the</p> <p>18 specific documents related to cGMP violations, the</p> <p>19 products that I looked -- the manufacturers that I</p> <p>20 looked at were Zhejiang --</p> <p>21 MR. HONIK: You can say ZHP. ZHP.</p> <p>22 THE WITNESS: ZHP. Thank you.</p> <p>23 ZHP and the FDA warning letters</p> <p>24 related to that. Mylan, in multiple ways, and</p> <p>25 Aurobindo, Torrent, Hetero and Lantech.</p>

24 (Pages 90 - 93)

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 94</p> <p>1 THE COURT REPORTER: What was the last 2 one? 3 THE WITNESS: And Lantech. 4 BY MR. GOLDBERG: 5 Q Yes or no, the documents that you 6 relied on for the pervasive deficiencies that you 7 referred to, are the complaint and the exhibits 8 attached to the complaint? 9 MR. HONIK: Object to the form, asked 10 and answered. 11 THE WITNESS: Okay. So I have 12 answered your question a bunch of times. So 13 again, there's -- 14 MR. GOLDBERG: I'm going to strike 15 the -- I'm going to withdraw the question. 16 Counsel, we're going to off the record. 17 THE VIDEOGRAPHER: The time is 12:46. 18 We are going off the record. 19 (Whereupon, a discussion was held off 20 the record.) 21 MR. HONIK: Let's proceed on the 22 stenographic record. Are we off the video 23 record? 24 THE VIDEOGRAPHER: We are off the 25 video.</p>	<p style="text-align: right;">Page 96</p> <p>1 see that? 2 A Yes. 3 Q Were there any particular reasons that 4 you were asked to assume that are listed here? 5 MR. HONIK: Object to the form of the 6 question. 7 THE WITNESS: All of them. So the -- 8 my -- I was -- hold on. 9 MR. HONIK: She's responding to your 10 question. Please stop interrupting her. 11 THE WITNESS: So I -- thank you. 12 I was asked to assume these products 13 were misbranded. This paragraph, Paragraph 23 14 in my report, lists the definition of 15 "misbranding" according to the 16 Food and Drug Administration. And the 17 definition is inclusive. 18 BY MR. GOLDBERG: 19 Q So you were asked to assume that all 20 of these particular reasons that a drug can be 21 misbranded applied to the valsartan in this case? 22 MR. HONIK: Objection to form. 23 THE WITNESS: That is -- that is a 24 mischaracterization of my testimony. I was 25 asked to assume that these products at issue</p>
<p style="text-align: right;">Page 95</p> <p>1 MR. HONIK: Okay. Before we go back 2 on the video, is there anything else you need 3 to say, Seth? I don't want to waste more time. 4 MR. GOLDBERG: Well, you want me to 5 put it on the record, so I'm going to. 6 MR. HONIK: That's fine. Do you want 7 it on the video record? 8 MR. GOLDBERG: Sure. 9 MR. HONIK: Okay. Queue us, please, 10 Justin. 11 THE VIDEOGRAPHER: The time is 12:48. 12 We're back on the record. 13 BY MR. GOLDBERG: 14 Q Let's turn to Paragraph 23 of your 15 report. In this paragraph, you refer -- 16 A Hold on. I'm not there yet. Hold on. 17 Paragraph 23 or Page 23? 18 Q Paragraph 23. 19 A Great. Thank you. Okay. Just give 20 me one second. 21 Q In this paragraph -- 22 A Just give me -- just give me one 23 second. Okay. 24 Q In this paragraph, you're referring to 25 reasons the FDA deems a drug as misbranded. Do you</p>	<p style="text-align: right;">Page 97</p> <p>1 were misbranded. And paragraph 23 is providing 2 a definition by the FDA of what "misbranded" 3 means. 4 BY MR. GOLDBERG: 5 Q And my particular question is, were 6 you asked to assume that any of these particular 7 reasons occurred with respect to the at-issue 8 valsartan products? 9 MR. HONIK: Object to the form, asked 10 and answered. 11 THE WITNESS: I was asked to assume 12 that the at-issue valsartan products were 13 misbranded. "Misbranded" is defined by the 14 U.S. Food and Drug Administration in a very 15 particular way. And that definition is 16 provided in Paragraph 23 of my report. 17 BY MR. GOLDBERG: 18 Q Looking at Paragraph 23, which of 19 these specific reasons for misbranding do you 20 believe applied in this -- with respect to the 21 at-issue valsartan products? 22 MR. HONIK: Object to the form, asked 23 and answered. 24 THE WITNESS: The complaint uses the 25 term "misbranded." From the perspective of</p>

25 (Pages 94 - 97)

RESTRICTED CONFIDENTIAL

Page 98	Page 100
<p>1 regulation of pharmaceutical industry, there is</p> <p>2 a particular definition of misbranding that the</p> <p>3 U.S. Food and Drug Administration uses. My</p> <p>4 understanding, and what I was asked to assume,</p> <p>5 is that the term "misbranded" is specific to</p> <p>6 the U.S. Food and Drug Administration's</p> <p>7 definition. And the definition is listed here</p> <p>8 and is inclusive.</p> <p>9 BY MR. GOLDBERG:</p> <p>10 Q You -- you understand that a</p> <p>11 misbranding can occur for any one of these reasons,</p> <p>12 right?</p> <p>13 A Again, I was asked to assume that</p> <p>14 these products were misbranded.</p> <p>15 The definition of "misbranding" by the</p> <p>16 U.S. Food and Drug Administration is provided here,</p> <p>17 and it's inclusive.</p> <p>18 Q So you don't agree with my question?</p> <p>19 You don't agree that any one of these that are</p> <p>20 listed in 20 -- in Paragraph 23 could be a reason</p> <p>21 for misbranding?</p> <p>22 MR. HONIK: Object to form, asked and</p> <p>23 answered.</p> <p>24 THE WITNESS: Okay. The FDA has a</p> <p>25 very specific definition of "misbranded." It</p>	<p>1 MR. GOLDBERG: No. Counsel --</p> <p>2 MR. HONIK: No.</p> <p>3 MR. GOLDBERG: Counsel, let me just</p> <p>4 say that you -- you are interfering with this</p> <p>5 deposition, and the witness is clearly</p> <p>6 filibustering. And we will -- we will not</p> <p>7 continue with this. Judge Vanaskie has been</p> <p>8 very clear that he will not permit</p> <p>9 filibustering by witnesses, period. He's</p> <p>10 actually sanctioned witnesses for it. And if</p> <p>11 we have to do it, we will get him on the phone</p> <p>12 for this.</p> <p>13 I tried to do this with you off the</p> <p>14 record, but you refused. I tried to do this in</p> <p>15 a way that would not color the testimony, but</p> <p>16 you did not want to do that. You wanted it on</p> <p>17 the record. The reality is, as the last five</p> <p>18 questions will demonstrate, this witness is</p> <p>19 filibustering and not answering the questions</p> <p>20 that are being asked. Period.</p> <p>21 MR. HONIK: It seems to me with the</p> <p>22 last five questions --</p> <p>23 MR. GOLDBERG: If you want to continue</p> <p>24 in this way, we will conclude the deposition</p> <p>25 with a call to Judge Vanaskie.</p>
Page 99	Page 101
<p>1 is stated here. In my Paragraph 23 of my</p> <p>2 report, it says, "Reasons that the FDA deems a</p> <p>3 drug as misbranded include, but are not limited</p> <p>4 to:" and then it enumerates the specifics. I'd</p> <p>5 be happy to go on and provide those</p> <p>6 specifics --</p> <p>7 BY MR. GOLDBERG:</p> <p>8 Q So I'm asking you --</p> <p>9 MR. HONIK: Don't interrupt the</p> <p>10 witness. Don't interrupt the witness.</p> <p>11 BY MR. GOLDBERG:</p> <p>12 Q I would like you to --</p> <p>13 MR. GOLDBERG: I'm not interrupting</p> <p>14 her.</p> <p>15 MR. HONIK: Do not interrupt the</p> <p>16 witness.</p> <p>17 BY MR. GOLDBERG:</p> <p>18 Q I would like to you answer my</p> <p>19 question.</p> <p>20 MR. HONIK: If you persist in</p> <p>21 interrupting the witness in the middle of her</p> <p>22 responses, we will conclude the deposition.</p> <p>23 She was in the middle of her response.</p> <p>24 Ms. Moskowitz, can you please read</p> <p>25 back the question and the answer?</p>	<p>1 MR. HONIK: What the last five</p> <p>2 questions and responses revealed to me is your</p> <p>3 ignorance in understanding the witness, full</p> <p>4 stop. We will not proceed until and unless you</p> <p>5 allow the witness to complete her responses,</p> <p>6 even if you don't like them.</p> <p>7 Accordingly, I will ask the reporter</p> <p>8 to read the pending question and as much as</p> <p>9 Dr. Conti's response as she has so that she may</p> <p>10 complete her response. And then you should</p> <p>11 feel free to ask another question.</p> <p>12 Ms. Moskowitz?</p> <p>13 COURT REPORTER: Sure.</p> <p>14 (Whereupon, the answer was read back</p> <p>15 as requested.)</p> <p>16 MR. HONIK: Do you wish to complete</p> <p>17 your response, Dr. Conti, or have you lost your</p> <p>18 train of thought?</p> <p>19 THE WITNESS: I have not lost my train</p> <p>20 of thought, but I don't have to...</p> <p>21 So, again, I was asked to assume that</p> <p>22 these products were misbranded. "Misbranded"</p> <p>23 from the FDA's perspective has its very</p> <p>24 specific definition that's enumerated -- that's</p> <p>25 listed in Paragraph 23. And that -- that</p>

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<p style="text-align: right;">Page 102</p> <p>1 definition of "misbranded" is inclusive. 2 BY MR. GOLDBERG: 3 Q Let's try it like this: Which -- 4 which of these enumerated factors of misbranding 5 apply to the at-issue products -- the at-issue 6 valsartan products? 7 MR. HONIK: Objection, asked and 8 answered and outside the scope of her report. 9 You may respond. 10 THE WITNESS: I was asked to assume 11 these products were misbranded, and -- and 12 again, that the definition of "misbranded" was 13 inclusive of all, but -- but not limited to 14 these factors. 15 BY MR. GOLDBERG: 16 Q So you weren't asked to assume any 17 particular fact -- any particular reason for 18 misbranding. You were just asked to assume 19 misbranding based on the definition of 20 "misbranding"? 21 MR. HONIK: Object to form, asked and 22 answered. 23 BY MR. GOLDBERG: 24 Q And -- 25 COURT REPORTER: I'm sorry. I didn't</p>	<p style="text-align: right;">Page 104</p> <p>1 BY MR. GOLDBERG: 2 Q So you were asked to assume the drugs 3 were adulterated based on all of the different 4 factors the FDA might consider a drug adulterated? 5 MR. HONIK: Object to the form. 6 BY MR. GOLDBERG: 7 Q Those listed -- those listed here and 8 those that are not listed here? 9 MR. HONIK: Object to the form, asked 10 and answered. 11 THE WITNESS: Again, I was -- so any 12 one of these factors can make a product 13 adulterated in the view of the FDA, just like 14 any one of these factors could be considered -- 15 would make a product misbranded, according to 16 Paragraph 23 and -- and beyond. 17 I was asked to assume that these 18 products are considered to be adulterated and 19 misbranded according to the FDA's definition, 20 which is inclusive of all of the factors 21 listed, both in my report and alluded to -- and 22 alluded to as additional. 23 BY MR. GOLDBERG: 24 Q Let's turn back to Paragraph 6 of your 25 report. It's on Page 3 of your report.</p>
<p style="text-align: right;">Page 103</p> <p>1 hear a response. 2 THE WITNESS: Correct. 3 COURT REPORTER: Thank you. 4 BY MR. GOLDBERG: 5 Q And if you -- if you look at the -- 6 the immediately preceding paragraph, Paragraph 22, 7 you provide the reasons the FDA deems a drug 8 adulterated, correct? 9 A I -- no. That is not what the 10 paragraph states. The paragraph states the reasons 11 the FDA deems a drug adulterated to include, but not 12 be limited to factors that are listed here. 13 Q And is the same true with respect to 14 adulteration, that you were asked to assume the 15 drugs were adulterated based on the definition of 16 "adulterated" as we see it here? 17 MR. HONIK: Object to form. 18 THE WITNESS: The FDA has a very 19 specific definition of "adulteration," which is 20 listed here, but again, it's inclusive. I was 21 asked to assume that adulteration -- that the 22 use of the term "adulteration" in the -- in the 23 complaint is inclusive of these factors and the 24 other factors that the FDA considers a product 25 to be adulterated.</p>	<p style="text-align: right;">Page 105</p> <p>1 Here you say -- and I'm looking in the 2 middle of the paragraph -- "Prescription drugs that 3 are adulterated and misbranded are neither 4 recognized by the United States government as 5 legitimate products to be sold by manufacturers nor 6 paid for by payors; nor are they considered 7 legitimate products by the pharmaceutical industry." 8 What do you mean by "legitimate 9 products"? 10 A I mean that a product that does not 11 meet cGMP regulations cannot be entered into the 12 legal class of trade into the United States 13 pharmaceutical trade. That means that pharmacies 14 can't sell products that don't meet cGMP practices 15 and standards, and nor can -- and nor do payors pay 16 for product -- 17 COURT REPORTER: And nor do payors... 18 THE WITNESS: Pay for products that do 19 not meet cGMP. 20 BY MR. GOLDBERG: 21 Q Is it -- is it the fact that there's a 22 cGMP violation that makes the product not 23 legitimate, or is it the fact that, as you put it, 24 pharmacies wouldn't pay for it, that consumers 25 wouldn't pay for it? What makes the product not</p>

27 (Pages 102 - 105)

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<p style="text-align: right;">Page 106</p> <p>1 legitimate?</p> <p>2 MR. HONIK: Object to form, asked an</p> <p>3 answered.</p> <p>4 THE WITNESS: Violation of cGMP.</p> <p>5 Remember -- and -- and also just to</p> <p>6 make sure that I understand your question,</p> <p>7 payors pay for products, consumers and</p> <p>8 insurers, right? Pharmacies may stock products</p> <p>9 for sale.</p> <p>10 BY MR. GOLDBERG:</p> <p>11 Q Is it your understanding that any cGMP</p> <p>12 violation would make a product not legitimate?</p> <p>13 MR. HONIK: Object to form, outside</p> <p>14 the scope of her report.</p> <p>15 You may answer.</p> <p>16 THE WITNESS: Manufacturers must</p> <p>17 attest to their compliance with cGMP practices</p> <p>18 in order to enter their products into the U.S.</p> <p>19 class of trade and then throughout the</p> <p>20 pharmaceutical supply chain, both as a</p> <p>21 condition of sale into the U.S. and then</p> <p>22 yearly.</p> <p>23 BY MR. GOLDBERG:</p> <p>24 Q Okay. Is it -- is it your</p> <p>25 understanding that any cGMP violation would make the</p>	<p style="text-align: right;">Page 108</p> <p>1 THE WITNESS: That is not my</p> <p>2 testimony, sir.</p> <p>3 BY MR. GOLDBERG:</p> <p>4 Q So a product that has a cGMP violation</p> <p>5 could be a legitimate product, in your view?</p> <p>6 MR. HONIK: Object to the form, asked</p> <p>7 and answered, beyond the scope.</p> <p>8 THE WITNESS: Again -- thank you.</p> <p>9 Again, pharmacy manufacturers cannot</p> <p>10 enter their products into the U.S. -- the</p> <p>11 closed U.S. chain of pharmaceutical products</p> <p>12 sold, bought, insured, consumed and -- by</p> <p>13 pharmacies, et cetera, if they do not meet</p> <p>14 cGMPs both upon launch -- they can't actually</p> <p>15 enter the U.S. market, and they can't sell over</p> <p>16 time unless they make the attestation that</p> <p>17 their products are cGMP compliant.</p> <p>18 BY MR. GOLDBERG:</p> <p>19 Q Is it your testimony that products</p> <p>20 produced by a manufacturer where there are cGMP</p> <p>21 violations cannot be sold in the U.S.?</p> <p>22 MR. HONIK: Object to the form, asked</p> <p>23 and answered.</p> <p>24 THE WITNESS: Okay. Again, a</p> <p>25 pharmaceutical manufacturer cannot --</p>
<p style="text-align: right;">Page 107</p> <p>1 product not legitimate?</p> <p>2 MR. HONIK: Object to form.</p> <p>3 BY MR. GOLDBERG:</p> <p>4 Q In your view?</p> <p>5 MR. HONIK: Object to form, asked and</p> <p>6 answered, beyond the scope.</p> <p>7 THE WITNESS: So, again -- again, my</p> <p>8 understanding is that pharmaceutical</p> <p>9 manufacturers that want to sell their product</p> <p>10 into the closed pharmaceutical chain in the</p> <p>11 United States must attest that their products</p> <p>12 meet cGMP. But when they first enter and</p> <p>13 launch into the market, that's a conditional on</p> <p>14 launch -- that their launch is conditional on</p> <p>15 that attestation. And then annually</p> <p>16 thereafter.</p> <p>17 THE COURT REPORTER: And then</p> <p>18 annually, they're...</p> <p>19 THE WITNESS: Thereafter.</p> <p>20 COURT REPORTER: Okay.</p> <p>21 BY MR. GOLDBERG:</p> <p>22 Q So it's your testimony that any cGMP</p> <p>23 violation would make a product not legitimate?</p> <p>24 MR. HONIK: Object to the form, asked</p> <p>25 and answered.</p>	<p style="text-align: right;">Page 109</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q My question is a yes or no question.</p> <p>3 MR. HONIK: You're interrupting the</p> <p>4 witness.</p> <p>5 MR. GOLDBERG: I am because my</p> <p>6 question is yes or no question.</p> <p>7 MR. HONIK: The witness is permitted</p> <p>8 to answer it in whatever manner she believes is</p> <p>9 appropriate. You have interrupted her.</p> <p>10 MR. GOLDBERG: Actually -- actually,</p> <p>11 that's not what happens under the rules in this</p> <p>12 case. If it's a yes or no question, the</p> <p>13 witness should say yes or no and then qualify</p> <p>14 their answer if need be.</p> <p>15 MR. HONIK: Yeah. Whatever you</p> <p>16 believe is -- is fine, Seth. You're not to</p> <p>17 interrupt her. If you persist in interrupting</p> <p>18 her, then we'll have to stop the deposition.</p> <p>19 But as far as I can see, you have asked her the</p> <p>20 same question a half dozen times. She's --</p> <p>21 she's being quite level with you in responding.</p> <p>22 I'm protecting the record.</p> <p>23 Madam reporter, let's have the</p> <p>24 question, and we'll have Dr. Conti answer it</p> <p>25 again.</p>

28 (Pages 106 - 109)

RESTRICTED CONFIDENTIAL

Page 110	Page 112
<p>1 (Whereupon, the question was read back 2 as requested.) 3 MR. HONIK: And then I've noted my 4 objection. 5 You can respond, Dr. Conti. 6 THE WITNESS: Thank you. 7 Pharmaceutical manufacturers are not 8 allowed to sell their products into the U.S. 9 without meeting cGMP standards both upon their 10 launch and over time. And just to be really 11 clear, it is -- from -- from the 12 U.S. regulator's perspective, it is on the 13 manufacturer to ensure and to attest that they 14 are manufacturing their products to the gold 15 standard of cGMP that is -- as outlined by the 16 U.S. Food and Drug Administration. 17 BY MR. GOLDBERG: 18 Q Is it -- do you -- is it your view 19 that -- is it your understanding that any cGMP 20 violation would prevent a manufacturer from selling 21 the product in the case -- in the U.S.? 22 MR. HONIK: Object to form, asked and 23 answered and beyond the scope. 24 You may respond. 25 THE WITNESS: Again --</p>	<p>1 MR. GOLDBERG: Why don't we -- 2 THE WITNESS: I think there's a 3 pending question. Would you like me the answer 4 it? 5 MR. GOLDBERG: No, I will withdraw 6 that. I can withdraw that question. 7 THE WITNESS: Okay. May I ask -- I'm 8 not sure what time it is in the real world. 9 MR. HONIK: It's 1:12 p.m. Is this a 10 good time to break for lunch, Dr. Conti? 11 MR. GOLDBERG: Sure. 12 THE WITNESS: That would be great. 13 Thank you. 14 MR. HONIK: And for your comfort, how 15 much time would you like? 16 THE WITNESS: Can we have half an 17 hour, please? 18 MR. HONIK: Yes. So we'll resume at 19 1:45. 20 THE WITNESS: Thank you. 21 THE VIDEOGRAPHER: The time is 1:13. 22 This ends Media Unit Number 2. We're going off 23 the record. 24 (Whereupon, a lunch recess was taken.) 25 THE VIDEOGRAPHER: The time is 1:53.</p>
Page 111	Page 113
<p>1 MR. GOLDBERG: When you say "beyond 2 the scope" -- can I just get a clarification 3 counsel? When you say "beyond the scope," what 4 do you mean? 5 MR. HONIK: Happily. You've 6 established that Dr. Conti was retained to 7 provide opinions and calculations regarding the 8 injury and damages incurred by classes of 9 consumers and end-payors in this matter. 10 To do so, she was assigned -- she must 11 assign an economic value to prescription drugs 12 that were adulterated and misbranded, two terms 13 that she's now defined for you, as outlined in 14 the complaint. As such, she's not our cGMP 15 expert. We have such an expert. He's been 16 deposed. And I'm merely pointing out to you 17 that if you want to drill down on cGMP 18 standards beyond what Dr. Conti, as a health 19 economist, needs to know, I think you're 20 wasting time. 21 But more importantly, it's beyond the 22 scope of her expertise and her report, which 23 you, yourself, established about two hours ago. 24 That's the basis for my objection when 25 I say "beyond the scope." Let's proceed.</p>	<p>1 This begins Media Unit Number 3. We're back on 2 the record. 3 BY MR. GOLDBERG: 4 Q Dr. Conti, if you look at Paragraph 6 5 of your report -- 6 A Just one second. Let me get it. 7 Okay. 8 Q The last sentence in this paragraph, 9 you use the phrase, "non-product status." What do 10 you mean by "non-product status"? 11 A Only prescription drugs -- only 12 products that have met the evidentiary standard for 13 cGMP, in addition to safety and efficacy, are 14 allowed to be sold into the U.S. market trade. 15 So products that do not meet that 16 standard of being manufactured to good manufacturing 17 practices -- or according to good manufacturing 18 practices, plus are safe and efficacious, are 19 allowed to be sold into the -- into the U.S. product 20 market. Those that do not meet that standard are 21 not -- are not -- according -- according to the 22 U.S. Food and Drug Administration, would be not 23 allowed. 24 Q When you use the terms "safety" and 25 "efficacy," can you explain what you mean by the</p>

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 114</p> <p>1 term -- by each of those terms?</p> <p>2 A All right. Again, this is a -- this</p> <p>3 is one of the most highly regulated consumer product</p> <p>4 markets, and so the FDA has very specific</p> <p>5 definitions of "safety" and "efficacy."</p> <p>6 What I mean here is that the product</p> <p>7 is judged to be safe and efficacious according to</p> <p>8 the U.S. Food and Drug Administration's rules.</p> <p>9 Q You don't have an independent</p> <p>10 understanding of safety and efficacy? It's just</p> <p>11 based on what the FDA would determine to be safe and</p> <p>12 effective?</p> <p>13 MR. HONIK: Object to the form.</p> <p>14 THE WITNESS: For my purposes in this</p> <p>15 report, correct. The definitions I'm using of</p> <p>16 safety and efficacy and meeting cGMP are those</p> <p>17 that relate to the</p> <p>18 Food and Drug Administration's definitions.</p> <p>19 BY MR. GOLDBERG:</p> <p>20 Q If you scroll down -- or if you go</p> <p>21 down to Paragraph 7 -- I know you have a hard copy</p> <p>22 in front of you. The last sentence of this</p> <p>23 paragraph, you say, "Prescription drugs that are</p> <p>24 adulterated and misbranded have no economic value.</p> <p>25 They are worthless."</p>	<p style="text-align: right;">Page 116</p> <p>1 efficacious as -- as attested to in the drug's</p> <p>2 manufacturing report to the</p> <p>3 Food and Drug Administration.</p> <p>4 BY MR. GOLDBERG:</p> <p>5 Q So products that have such an</p> <p>6 attestation have value, right?</p> <p>7 MR. HONIK: Object to form.</p> <p>8 THE WITNESS: You mischaracterized my</p> <p>9 testimony.</p> <p>10 BY MR. GOLDBERG:</p> <p>11 Q I'm asking you a question. Products</p> <p>12 that have the attestation you described have value,</p> <p>13 correct?</p> <p>14 MR. HONIK: Object to form.</p> <p>15 THE WITNESS: Okay. Again,</p> <p>16 prescription -- pharmaceutical manufacturers</p> <p>17 are not allowed to sell products into the U.S.</p> <p>18 market that are not produced in a manner of</p> <p>19 cGMP compliant, plus are safe and efficacious</p> <p>20 as judged by the Food and Drug Administration.</p> <p>21 There is a long and very complicated</p> <p>22 route for a product to be judged, a drug, a</p> <p>23 prescription drug, that is allowed to be</p> <p>24 entered into the U.S. class of trade.</p> <p>25 Manufacturers have to meet all of those</p>
<p style="text-align: right;">Page 115</p> <p>1 What do you mean by "worthless"?</p> <p>2 A I mean this is in --</p> <p>3 COURT REPORTER: You mean this in...</p> <p>4 THE WITNESS: Thank you.</p> <p>5 I mean this in -- in economic sense,</p> <p>6 that there is no legitimate supply curve of</p> <p>7 products -- of products that do not meet the</p> <p>8 standard of cGMP in addition to being --</p> <p>9 THE COURT REPORTER: In addition to</p> <p>10 being...</p> <p>11 THE WITNESS: Judged safe and</p> <p>12 efficacious by the</p> <p>13 Food and Drug Administration.</p> <p>14 BY MR. GOLDBERG:</p> <p>15 Q Is it -- is it your view that there's</p> <p>16 no degree of adulteration when it comes to</p> <p>17 worthlessness and that all adulterated drugs, for</p> <p>18 any reason, are worthless?</p> <p>19 MR. HONIK: Object to form.</p> <p>20 THE WITNESS: So my understanding is</p> <p>21 that in order to be allowed to be sold into the</p> <p>22 U.S. supply chain of prescription drugs, the</p> <p>23 manufacturer needs to attest that these</p> <p>24 products are manufactured according to cGMP, at</p> <p>25 minimum, and in addition, are safe and</p>	<p style="text-align: right;">Page 117</p> <p>1 standards, both in terms of attestation -- in</p> <p>2 other words, they can say these things, but</p> <p>3 they -- but they are also judged by the</p> <p>4 regulator itself about whether or not these</p> <p>5 things are actually --</p> <p>6 THE COURT REPORTER: Are actually...</p> <p>7 THE WITNESS: True.</p> <p>8 BY MR. GOLDBERG:</p> <p>9 Q So products that are sold with that</p> <p>10 attestation have value?</p> <p>11 MR. HONIK: Object to form, asked and</p> <p>12 answered.</p> <p>13 THE WITNESS: Okay. Again, it's not</p> <p>14 just the attestation that matters. The U.S.</p> <p>15 regulator requires that any products that want</p> <p>16 to be sold into the U.S. market that is going</p> <p>17 to be considered a prescription drug, must be</p> <p>18 produced in accordance with cGMP and be safe</p> <p>19 and efficacious. And the manufacturer just --</p> <p>20 can't just say that. They actually have to</p> <p>21 prove it to the regulator.</p> <p>22 It is in that meaning that I mean that</p> <p>23 those products have value. In other words,</p> <p>24 products that -- I can say it in a different</p> <p>25 way, which is products have value. There is a</p>

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 118</p> <p>1 legitimate supply curve if and only if they are 2 produced according to cGMP and are safe and 3 efficacious, both by attestation and by 4 proof -- by empirical proof. 5 BY MR. GOLDBERG: 6 Q If the FDA is permitting those 7 products to be sold, they have value? 8 A For prescription drugs, drugs that are 9 actually called "drugs" by the 10 Food and Drug Administration, they -- and are sold 11 at pharmacies, and dispensed to American patients by 12 physicians or by pharmacy chains, those products 13 must meet the evidentiary standard of, they are 14 produced according to cGMP, they are not adulterated 15 or misbranded, and they are safe and efficacious, 16 for the -- for the disease -- specific indication 17 that the Food and Drug Administration approves that 18 product for. 19 COURT REPORTER: I'm sorry. The 20 Food and Drug Administration... 21 THE WITNESS: Approves that product to 22 be sold for or used for. 23 BY MR. GOLDBERG: 24 Q So if the FDA has permitted -- 25 if -- permitted prescription drugs to be sold at</p>	<p style="text-align: right;">Page 120</p> <p>1 hold on. It's actually on the manufacturer to 2 ensure that that product is what it says it is on 3 the product's -- on the product's label. 4 BY MR. GOLDBERG: 5 Q Okay. So you -- you seem to be 6 emphasizing the word "enter." Is there some 7 particular emphasis you're putting on that? 8 A I don't -- I'm not sure what you mean 9 by that question. 10 Q You keep saying the FDA will not 11 allow -- a manufacturer cannot -- you -- you -- what 12 you said is drugs cannot enter into the U.S. class 13 of trade without meeting the evidentiary standard. 14 What do you mean by "enter into the U.S. class of 15 trade"? 16 A I mean they are not allowed to be sold 17 into the U.S. market without meeting the evidentiary 18 standard of being produced, at minimum, by cGMP and 19 meeting other evidentiary standards, as well. 20 Q So what are the evidentiary standards 21 that you're referring to? You have cGMP violations. 22 A I'm confused. 23 Q You used the phrase "evidentiary 24 standard" in the four -- in your last four answers. 25 What are the evidentiary standards you're referring</p>
<p style="text-align: right;">Page 119</p> <p>1 pharmacies, you would agree that those drugs have a 2 value? 3 MR. HONIK: Object to form, asked and 4 answered. 5 THE WITNESS: Well, wait. So it's not 6 just that. So again, according to the 7 regulator, a prescription drug is not allowed 8 to enter into the U.S. class of trade, sold to 9 a consumer, covered by a manufacturer -- or by 10 an insurer, unless they meet the evidentiary 11 standard of -- of being produced in accordance 12 with cGMP at a minimum, and meet other 13 requirements, as well. 14 BY MR. GOLDBERG: 15 Q Are you aware of any instance where a 16 drug was sold, but it did not meet the minimum, as 17 you put it, cGMP requirements? 18 A Again, drugs cannot enter into the 19 U.S. class of trade without meeting the evidentiary 20 standard. What I mean by that is the FDA will not 21 approve a drug to enter into the U.S. class of trade 22 without meeting the evidentiary standard and the 23 manufacturer attesting that they are meeting that 24 standard. 25 It is actually on the manufacturer --</p>	<p style="text-align: right;">Page 121</p> <p>1 to? 2 MR. HONIK: Object to form, asked and 3 answered and beyond the scope of her report. 4 THE WITNESS: Okay. So you can look 5 at Paragraph 6 of my report, "Federal law, as 6 codified by regulations of the 7 Food and Drug Administration, mandates that 8 prescription drugs be produced in accordance 9 with cGMP to ensure that the drugs meet the 10 legal requirements of safety and that they have 11 the quality, purity, identity and strength they 12 are represented to conduct." 13 That's what I mean by the evidentiary 14 standard of being sold into the U.S. or being 15 legitimate products. 16 BY MR. GOLDBERG: 17 Q Let's take each one of those. What do 18 you understand the term "quality," as you've used 19 it, to mean? 20 A Quality is a process, from the 21 U.S. Food and Drug Administration's perspective, so 22 the print is both what it says it is, but it's also 23 manufactured in a process that is a quality 24 manufacturing process that meets cGMP. 25 Q What do you understand the term</p>

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 122</p> <p>1 "purity" to mean, as you're using it?</p> <p>2 A I mean, again, it's in accordance with</p> <p>3 the Food and Drug Administration's definition of it.</p> <p>4 So purity, identity and strength are all the FDA's</p> <p>5 definition.</p> <p>6 Q Okay. You're -- so you're -- when</p> <p>7 you're using the term, you're really -- you're just</p> <p>8 saying based on how the FDA defines these terms?</p> <p>9 A Yes.</p> <p>10 Q Correct?</p> <p>11 A Exactly. Just like my use of the term</p> <p>12 "adulterated," my use of the term "misbranded," they</p> <p>13 are all related to the U.S. government's definition</p> <p>14 inclusive of how these terms are actually being --</p> <p>15 being used.</p> <p>16 Q How these terms are being written in</p> <p>17 the regulations, that's what you're referring to?</p> <p>18 A Correct.</p> <p>19 Q I still want to understand. If a</p> <p>20 drug -- if a prescription drug is being sold -- so</p> <p>21 there's a supply for it. And people are buying it,</p> <p>22 so there's a demand for it. Does it -- is it still</p> <p>23 worthless if it doesn't meet some of these</p> <p>24 evidentiary standards?</p> <p>25 MR. HONIK: Object to form.</p>	<p style="text-align: right;">Page 124</p> <p>1 And I am just confirming. So you're</p> <p>2 not thinking about it in terms of demand, you're</p> <p>3 thinking about it in terms of supply?</p> <p>4 A What is "it" in your question?</p> <p>5 Q The -- the question of whether the</p> <p>6 drug is -- a drug is worthless?</p> <p>7 A So, again, from an economic</p> <p>8 perspective, there is no legitimate supply curve for</p> <p>9 a product that is adulterated and misbranded. That</p> <p>10 is by statute. Consumers can demand products that</p> <p>11 are illegal or illegitimate, but they're -- but a</p> <p>12 pharmacy can't sell a product that does not -- for</p> <p>13 which the manufacturer has not met the evidentiary</p> <p>14 standard and have been approved by the U.S.</p> <p>15 regulator for use in that -- in that context.</p> <p>16 Q Do you have any -- I don't see it</p> <p>17 here. Did you cite to any economic treatise for the</p> <p>18 notion that if there is -- there is no legitimate</p> <p>19 supply curve for a product that is adulterated and</p> <p>20 misbranded?</p> <p>21 A This is one of the most -- one of the</p> <p>22 most highly regulated consumer product markets</p> <p>23 that -- that exists in the United States. U.S.</p> <p>24 is -- maintains the gold standard for quality of its</p> <p>25 prescription drug supply.</p>
<p style="text-align: right;">Page 123</p> <p>1 THE WITNESS: My statement is one</p> <p>2 related to the supply curve, not the demand</p> <p>3 curve. By definition, there is no supply of</p> <p>4 drugs -- of product that do not meet the</p> <p>5 definition of a "drug" according to the</p> <p>6 Food and Drug Administration. In order for a</p> <p>7 manufacturer to sell a product that meets the</p> <p>8 definition of the term "drug," it must meet the</p> <p>9 evidentiary standards of meeting and attesting</p> <p>10 to the cGMP production and be safe and</p> <p>11 efficacious for the indicated use.</p> <p>12 BY MR. GOLDBERG:</p> <p>13 Q So the demand -- you're -- you're not</p> <p>14 considering demand in that analysis, you're focusing</p> <p>15 on --</p> <p>16 THE COURT REPORTER: Can you repeat</p> <p>17 that question, please?</p> <p>18 BY MR. GOLDBERG:</p> <p>19 Q You're not considering demand in your</p> <p>20 analysis, you're focusing on the supply?</p> <p>21 A In my analysis, I don't know what you</p> <p>22 mean by my -- "in my analysis."</p> <p>23 Q You said, "My statement is related to</p> <p>24 the supply curve, not the demand curve. By</p> <p>25 definition, there is no supply of drugs."</p>	<p style="text-align: right;">Page 125</p> <p>1 Every pharmaceutical manufacturer that</p> <p>2 sells products through to pharmacies and ultimately</p> <p>3 to American consumers, knows what the rules are.</p> <p>4 The rules are they must meet the evidentiary</p> <p>5 standard of permitting to quality manufacturing and</p> <p>6 be safe and efficacious.</p> <p>7 From an economic standpoint, that --</p> <p>8 it is meeting those regulations that allow there to</p> <p>9 be a supply of a product. I don't need to -- you</p> <p>10 can't think about the supply curve of prescription</p> <p>11 drugs without understanding what the regulation is</p> <p>12 that allows them to be sold to the U.S. That's</p> <p>13 your -- that's actually health economics 101.</p> <p>14 Q Well, I'm trying to understand which</p> <p>15 health economics 101 treatise or authority you're</p> <p>16 citing for the notion that -- because in your view,</p> <p>17 there's no legitimate supply curve, a drug is</p> <p>18 worthless?</p> <p>19 MR. HONIK: Object to form, asked and</p> <p>20 answered.</p> <p>21 I'm sorry. Please answer, Dr. Conti.</p> <p>22 THE WITNESS: Thank you.</p> <p>23 It's not my view. This is the U.S.</p> <p>24 regulator's perspective. The U.S. regulator</p> <p>25 does not -- does not view -- does not allow</p>

RESTRICTED CONFIDENTIAL

Page 126	Page 128
<p>1 drugs to be sold into the U.S. market that do 2 not meet the evidentiary standard. And it's 3 prescription drug manufacturers themselves that 4 have wanted that standard to be as it is. 5 And so I -- I mean, there's plenty of 6 published literature that talks about this, the 7 importance of the evidentiary standard to the 8 supply of these products, and I cite some of 9 that in my report. But every pharmaceutical 10 manufacturer that is allowed to sell into the 11 U.S. market knows what the standard is. 12 BY MR. GOLDBERG: 13 Q You're -- you're not answering my 14 question. My question is what economic support do 15 you have for the notion that, if there's no supply, 16 the drug is worthless? 17 MR. HONIK: Object to the form, asked 18 and answered. 19 THE WITNESS: This is economics 101. 20 If you go -- I'm more than happy to show you 21 the picture. But there can be no price for a 22 product that does not have a demand curve 23 meeting a supply curve. There is no economic 24 price if there is no legitimate supply curve. 25 There are plenty of economic textbooks</p>	<p>1 counsel, don't coach the witness. Don't 2 interfere. 3 MR. HONIK: This witness needs to be 4 heard -- 5 MR. GOLDBERG: Counsel, don't say a 6 word. The question is pending. Witness will 7 answer without your interruption. If you want 8 to say objection, you can say objection. 9 MR. HONIK: I will say as many words 10 as I deem appropriate -- 11 MR. GOLDBERG: If you want to say 12 objection to form, say it, but don't -- 13 MR. HONIK: I will protect the record 14 in the manner in which I see fit. 15 MR. GOLDBERG: No. You will interfere 16 with the record. 17 MR. HONIK: What I'm -- what I'm now 18 trying to do, because I believe you've asked 19 the witness the same exact question 6, 7, maybe 20 10 times, is to clarify. And if -- and if 21 you're asking a different question, then 22 perhaps she can answer it differently. I'm 23 simply trying to move things along. 24 Is your question whether or not 25 consumers, during the relevant period that</p>
Page 127	Page 129
<p>1 that explain that an economic price is related 2 to both demand and supply, and its -- and, you 3 know, its relationship to each other. 4 BY MR. GOLDBERG: 5 Q Was it -- there was an economic -- 6 there was an economic price that was paid for 7 valsartan between 2012 and 2018, right? 8 MR. HONIK: Object to the form. Are 9 you asking if consumers paid for it, paid for 10 this drug? 11 THE WITNESS: I don't understand what 12 you're asking. 13 MR. GOLDBERG: Counsel -- 14 BY MR. GOLDBERG: 15 Q I'm using your phrase, "economic 16 price." There was an economic price paid for 17 valsartan between 2012 and 2018, right? 18 MR. HONIK: Right. And our lawsuit 19 seeks -- 20 MR. GOLDBERG: Counsel, you're not -- 21 counsel, don't testify. Don't interrupt. Let 22 the witness answer the question. 23 MR. HONIK: You have now asked the 24 same question six times. 25 MR. GOLDBERG: Counsel, don't --</p>	<p>1 you've now raised, actually -- 2 MR. GOLDBERG: I want to ask my 3 question. Don't ask my question. 4 MR. HONIK: I know. I'm not -- 5 MR. GOLDBERG: No, stop. Ruben, stop. 6 It's improper, and stop. 7 MR. HONIK: Here is what we're going 8 to do. 9 MR. GOLDBERG: Stop it. 10 MR. HONIK: Here's what we're going to 11 do. Here's what we're going to do. 12 MR. GOLDBERG: Tell me what we're 13 going to do. 14 MR. HONIK: If you persist in asking 15 the same question again, then we will have to 16 stop. I think the witness has responded -- I 17 think the witness has responded completely to 18 your question. You seem not to understand -- 19 MR. GOLDBERG: The objection is asked 20 and answered. If that's your objection, say 21 it. 22 MR. HONIK: Is there a pending 23 question? 24 BY MR. GOLDBERG: 25 Q Dr. Conti -- Dr. Conti, there was an</p>

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<p style="text-align: right;">Page 130</p> <p>1 economic price that was paid for valsartan between 2 2012 and 2018, correct? 3 MR. HONIK: Object to form, asked and 4 answered. 5 THE WITNESS: Okay. Again, let's 6 start at the beginning. From my perspective, 7 prospectively, there may be a demand curve for 8 products that exist that cannot be met by a 9 legitimate supply curve. In -- you can't get 10 an economic price if there is not both a demand 11 curve and a legitimate supply curve. 12 In this matter, I was asked to assume 13 that these products at issue between 2012 and 14 2018 were adulterated and misbranded according 15 to the Food and Drug Administration's 16 definition. 17 By definition, if they were both 18 adulterated and misbranded, there is no 19 legitimate supply curve. And therefore, demand 20 and supply cannot meet, and there cannot be an 21 economic price. 22 BY MR. GOLDBERG: 23 Q But demand and supply did meet, and an 24 economic price was paid for valsartan between 2012 25 and 2018, wasn't there?</p>	<p style="text-align: right;">Page 132</p> <p>1 THE WITNESS: Again, I was asked to 2 assume that that supply was adulterated and 3 misbranded. 4 BY MR. GOLDBERG: 5 Q So the answer is, yes, there was a 6 supply? Leaving aside your assumptions, you agree 7 there was a supply of valsartan between 2012 and 8 2018? 9 MR. HONIK: Object to the form, asked 10 and answered. 11 THE WITNESS: I think what you're 12 asking is whether Diovan and Exforge, the 13 brand -- the branded products, plus the generic 14 drugs, were available to the U.S. market, were 15 available -- 16 THE COURT REPORTER: I'm sorry. You 17 cut out, Doctor. 18 Were available to... 19 THE WITNESS: To be purchased in the 20 U.S. supply chain between 2012 and 2018. If 21 that is your question, then the answer is yes. 22 BY MR. GOLDBERG: 23 Q Okay. And between 2012 and 2018, 24 valsartan -- that valsartan was purchased by 25 consumers and third-party payors, right?</p>
<p style="text-align: right;">Page 131</p> <p>1 MR. HONIK: Object to the form, asked 2 and answered. 3 Go ahead, Dr. Conti. You can explain 4 it again. 5 THE WITNESS: Again, consumers and 6 payors did not know that these products were 7 adulterated and misbranded during the relevant 8 time period. That's because, as I understand 9 it, the manufacturers, who are the defendants 10 in this case, were attesting that these 11 products were meeting the evidentiary standard 12 when they were not. 13 From my perspective in -- in analyzing 14 this market, if I assume that these products 15 are misbranded and adulterated, then there is 16 no legitimate supply curve. And therefore, 17 there is no meeting of demand and supply and no 18 economic price. 19 BY MR. GOLDBERG: 20 Q There was a supply for these drugs 21 between 2012 and 2018. You don't dispute that, do 22 you? 23 MR. HONIK: Object to the form, asked 24 and answered. 25 Go ahead.</p>	<p style="text-align: right;">Page 133</p> <p>1 A So consumers purchased Diovan and 2 Exforge and it's generic equivalents during that 3 time period. The at-issue drugs, I was asked to 4 assume were adulterated and misbranded during that 5 time period. 6 Q Do you have experience assessing the 7 clinical value of drugs? 8 A As an economist? Yes. As a doctor, 9 sadly, no. 10 Q Got you. 11 Have you conducted any clinical trials 12 with respect to drug -- to drugs, pharmaceutical 13 drugs? 14 A Have I conducted any clinical trials? 15 I have been involved in clinical trials that 16 have -- that are conducted -- 17 THE COURT REPORTER: That are 18 conducted... 19 THE WITNESS: On prescription drugs. 20 BY MR. GOLDBERG: 21 Q Have you reviewed the -- the -- strike 22 that. 23 You understand that valsartan is -- an 24 intended use of valsartan is to treat hypertension, 25 right?</p>

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 134</p> <p>1 A Yes. I mean, it is a member of a</p> <p>2 class of drug -- of a therapeutic class of drugs</p> <p>3 that are all intended to treat hypertension.</p> <p>4 Q And another intended use of valsartan</p> <p>5 is to treat heart failure?</p> <p>6 A I don't know that specifically.</p> <p>7 Q Are you aware that, if left untreated,</p> <p>8 high blood pressure can lead to heart attacks?</p> <p>9 MR. HONIK: Objection, outside the</p> <p>10 scope.</p> <p>11 THE WITNESS: I mean, like, as an</p> <p>12 American citizen who's relatively well</p> <p>13 informed, yes, I understand that.</p> <p>14 BY MR. GOLDBERG:</p> <p>15 Q Okay. And -- yeah, I'm looking for</p> <p>16 your understanding as Dr. Conti, whether that's in</p> <p>17 your individual capacity as an expert. But you</p> <p>18 understand that high blood pressure, if left</p> <p>19 untreated, can lead to heart attacks, right?</p> <p>20 A Yes. And I understand that there are</p> <p>21 many, many treatments to prevent heart attacks</p> <p>22 available.</p> <p>23 Q And if left untreated, high blood</p> <p>24 pressure can lead to strokes?</p> <p>25 MR. HONIK: Same objection, outside</p>	<p style="text-align: right;">Page 136</p> <p>1 the past two decades with the advent of stents,</p> <p>2 but also the advent of many prescription drugs</p> <p>3 that support their prevention and treatment.</p> <p>4 BY MR. GOLDBERG:</p> <p>5 Q There would be medical expenses</p> <p>6 attributable to a heart attack for most consumers,</p> <p>7 right?</p> <p>8 MR. HONIK: Same objection.</p> <p>9 THE WITNESS: Are you saying as a</p> <p>10 general matter that -- that heart attacks</p> <p>11 entail costs?</p> <p>12 BY MR. GOLDBERG:</p> <p>13 Q Yes.</p> <p>14 A Yes, definitively.</p> <p>15 Q And the same -- the same is true for</p> <p>16 strokes?</p> <p>17 A The primary prevention and treatment</p> <p>18 of strokes costs money.</p> <p>19 COURT REPORTER: It what?</p> <p>20 THE WITNESS: In the U.S.</p> <p>21 COURT REPORTER: I'm sorry. The</p> <p>22 primary prevention...</p> <p>23 THE WITNESS: And treatment of strokes</p> <p>24 in the U.S. costs money.</p> <p>25 COURT REPORTER: Thank you.</p>
<p style="text-align: right;">Page 135</p> <p>1 the scope of her report.</p> <p>2 THE WITNESS: Thank you.</p> <p>3 Again, I understand as, a general</p> <p>4 matter, that -- that high blood pressure is a</p> <p>5 risk factor for stroke and that high blood</p> <p>6 pressure can be treated in many different ways.</p> <p>7 BY MR. GOLDBERG:</p> <p>8 Q And if somebody has a heart attack,</p> <p>9 that can require hospitalization?</p> <p>10 MR. HONIK: Same objection.</p> <p>11 THE WITNESS: Yes. My mother had a</p> <p>12 heart attack, and she was hospitalized. I am</p> <p>13 generally aware of the facts.</p> <p>14 BY MR. GOLDBERG:</p> <p>15 Q And if somebody has a stroke, it can</p> <p>16 require hospitalization?</p> <p>17 MR. HONIK: Same objection.</p> <p>18 THE WITNESS: Yes. But again, there</p> <p>19 are many treatments -- I mean, we are so</p> <p>20 fortunate in the U.S. that there are so many</p> <p>21 treatments that prevent heart attack and</p> <p>22 strokes now from progressing to the point of</p> <p>23 requiring hospitalization or even, more</p> <p>24 tragically, death now. Deaths from strokes and</p> <p>25 heart attacks have dramatically come down over</p>	<p style="text-align: right;">Page 137</p> <p>1 BY COURT REPORTER:</p> <p>2 Q You'd agree that avoiding the</p> <p>3 complications from untreated hypertension could</p> <p>4 provide a value to a patient?</p> <p>5 MR. HONIK: Objection, outside the</p> <p>6 scope.</p> <p>7 THE WITNESS: As a general matter?</p> <p>8 BY MR. GOLDBERG:</p> <p>9 Q Yeah.</p> <p>10 A I think a lot of Americans would view</p> <p>11 the primary prevention and treatment of underlying</p> <p>12 conditions to prevent strokes and heart attacks is</p> <p>13 of value. I mean, I certainly view that as</p> <p>14 valuable.</p> <p>15 Q So if valsartan were treating</p> <p>16 someone's hypertension and that person, as a result,</p> <p>17 was avoiding a heart attack or a stroke because of</p> <p>18 their valsartan, that would be a value to that</p> <p>19 consumer?</p> <p>20 MR. HONIK: Object to form.</p> <p>21 THE WITNESS: That has therapeutic</p> <p>22 value. It doesn't have economic value from my</p> <p>23 reports on that.</p> <p>24 BY MR. GOLDBERG:</p> <p>25 Q So the consumer would get a</p>

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 138</p> <p>1 therapeutic benefit from the treatment of</p> <p>2 valsartan -- their treatment with valsartan?</p> <p>3 MR. HONIK: Object to the form,</p> <p>4 outside the scope.</p> <p>5 THE WITNESS: Yeah. I think that's a</p> <p>6 good question.</p> <p>7 So, again, from the perspective of my</p> <p>8 report, I was asked to assume that the</p> <p>9 valsartan products at issue were adulterated</p> <p>10 and misbranded, and therefore, they should not</p> <p>11 have entered into the U.S. class of trade.</p> <p>12 Whether those products provided</p> <p>13 therapeutic value is -- is not of -- it's</p> <p>14 not -- it doesn't matter for the purposes of my</p> <p>15 calculation.</p> <p>16 BY MR. GOLDBERG:</p> <p>17 Q Well, do you dispute that those</p> <p>18 products provided therapeutic value?</p> <p>19 MR. HONIK: Object to the form, asked</p> <p>20 and answered, outside the scope.</p> <p>21 THE WITNESS: I don't know. I</p> <p>22 don't -- I don't have an opinion. You know, as</p> <p>23 an economist, I don't have an opinion.</p> <p>24 BY MR. GOLDBERG:</p> <p>25 Q Are you aware of any studies showing</p>	<p style="text-align: right;">Page 140</p> <p>1 COURT REPORTER: Of no moment.</p> <p>2 M-o-m-e-n-t? Moment.</p> <p>3 THE WITNESS: Yes.</p> <p>4 THE COURT REPORTER: Thank you. Thank</p> <p>5 you.</p> <p>6 BY MR. GOLDBERG:</p> <p>7 Q Is it your testimony that positive</p> <p>8 health outcomes have no economic value to consumers?</p> <p>9 MR. HONIK: Object to the form, asked</p> <p>10 and answered, outside the scope.</p> <p>11 THE WITNESS: That is not my</p> <p>12 testimony, sir.</p> <p>13 BY MR. GOLDBERG:</p> <p>14 Q Do you agree that positive health</p> <p>15 outcomes can have economic value to consumers?</p> <p>16 MR. HONIK: Same objection.</p> <p>17 THE WITNESS: That is not my</p> <p>18 testimony, sir.</p> <p>19 BY MR. GOLDBERG:</p> <p>20 Q Do you agree that positive outcomes,</p> <p>21 health outcomes, can have economic value to</p> <p>22 consumers, yes or no?</p> <p>23 MR. HONIK: Same objection, asked and</p> <p>24 answered.</p> <p>25 THE WITNESS: Of what, sir?</p>
<p style="text-align: right;">Page 139</p> <p>1 that between 2012 and 2018, valsartan was not</p> <p>2 effective in treating hypertension?</p> <p>3 MR. HONIK: Object to the form, beyond</p> <p>4 the scope.</p> <p>5 THE WITNESS: No. But it's -- again,</p> <p>6 has no moment, in my analysis, because again, I</p> <p>7 was asked to assume that those products at</p> <p>8 issue were misbranded and adulterated, and</p> <p>9 therefore would not have entered into the U.S.</p> <p>10 class of trade.</p> <p>11 BY MR. GOLDBERG:</p> <p>12 Q Are you aware of any warnings by the</p> <p>13 FDA between 2012 and 2018 that patients shouldn't</p> <p>14 take valsartan because it's not effective in</p> <p>15 treating hypertension?</p> <p>16 MR. HONIK: Object to form, outside</p> <p>17 the scope.</p> <p>18 THE WITNESS: So, again, it's of no</p> <p>19 moment -- moment in my analysis and my</p> <p>20 assignment in this case.</p> <p>21 THE COURT REPORTER: What word are you</p> <p>22 using? Moment?</p> <p>23 THE WITNESS: It's no moment.</p> <p>24 MR. HONIK: It's of no moment, she</p> <p>25 said.</p>	<p style="text-align: right;">Page 141</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q Do you agree that controlled</p> <p>3 hypertension due to valsartan could have economic</p> <p>4 value to a consumer?</p> <p>5 A Same objection.</p> <p>6 THE WITNESS: I think I'm gonna -- I</p> <p>7 think I'm gonna ask just -- you to clarify.</p> <p>8 So do you mean that prescription-based</p> <p>9 control of hypertension could have value to</p> <p>10 consumers?</p> <p>11 BY MR. GOLDBERG:</p> <p>12 Q Yes.</p> <p>13 A There's my -- my -- my point is</p> <p>14 there's lots of -- I mean, my understanding is</p> <p>15 there's lots of ways that consumers can control</p> <p>16 their hypertension that go well beyond the</p> <p>17 availability of prescription valsartan.</p> <p>18 Q But my question dealt with</p> <p>19 prescription valsartan.</p> <p>20 A Okay.</p> <p>21 Q Yes or no, if prescription valsartan</p> <p>22 were controlling a patient's hypertension, could</p> <p>23 that provide economic value to the patient?</p> <p>24 MR. HONIK: Objection to form, asked</p> <p>25 and answered, outside the scope.</p>

RESTRICTED CONFIDENTIAL

Page 142	Page 144
<p>1 THE WITNESS: What do you mean by 2 "economic value"? 3 (Whereupon, there was a speaking 4 interruption.) 5 THE WITNESS: I'm sorry -- 6 THE COURT REPORTER: I'm sorry, who's 7 speaking? 8 MR. HONIK: There was a question and 9 objection and a partial answer from the 10 witness. Did you get any of that? 11 THE COURT REPORTER: Yes. 12 MR. HONIK: Okay. Great. 13 THE WITNESS: And there was, like, 14 something -- someone else started speaking. 15 MR. HONIK: And then someone 16 interjected. 17 THE WITNESS: Correct. In the middle 18 of my answer. 19 MR. HONIK: Okay. So other than Seth, 20 everyone -- and myself, everyone should be 21 muted. 22 BY MR. GOLDBERG: 23 Q Let me ask the question again. 24 Yes or no, prescription valsartan, 25 when controlling a patient's hypertension, could</p>	<p>1 MR. HONIK: Don't interrupt her. 2 THE WITNESS: I'm going to ask again. 3 I don't understand how you're using the term 4 "economic value." 5 BY MR. GOLDBERG: 6 Q If a patient saved money on their 7 health expenses because of their treatment with 8 at-issue valsartan products, would that have 9 provided economic value to the patient? 10 MR. HONIK: Is there a question? 11 MR. GOLDBERG: That is the question. 12 Should I ask it again? 13 MR. HONIK: No, Jamie can read it, and 14 we can all determine if it's a question. It 15 sounded like a statement. 16 But, Jamie, can you read it back. 17 MR. GOLDBERG: I'm going to 18 read -- I'm going to read the question. 19 BY MR. GOLDBERG: 20 Q If a patient saved money on their 21 health expenses because of their treatment with 22 at-issue valsartan products, would that have 23 provided an economic value to the patient? 24 MR. HONIK: Object to form, beyond the 25 scope, asked and answered.</p>
Page 143	Page 145
<p>1 that provide an economic value to the patient? 2 MR. HONIK: Object to form, asked and 3 answered, beyond the scope. 4 You can answer. 5 THE WITNESS: Thank you. Seth -- 6 Mr. Goldberg, what do you mean by "economic 7 value" in that question? 8 BY MR. GOLDBERG: 9 Q Well, before you had said that that 10 kind of control would provide a therapeutic benefit, 11 not an economic value. And I'm just asking -- you 12 used the phrase "economic value." What do you 13 understand it to mean? 14 MR. HONIK: Object to the form. 15 THE WITNESS: Okay. Again, I -- we 16 are talking about my definition of "economic 17 value" in this specific matter based on 18 assumptions that I was asked to make. You are 19 using "economic value" in a way that is not 20 consistent with how I just defined "economic 21 value" for the purposes of my report. So in 22 that -- 23 BY MR. GOLDBERG: 24 Q Doctor -- 25 THE WITNESS: Hold on.</p>	<p>1 You can respond. 2 THE WITNESS: Thank you. 3 MR. HONIK: As best you can. 4 THE WITNESS: Thank you. 5 So for the -- I mean, as a general 6 matter, if people are saving money, then there 7 is some economic -- there might be economic 8 value. That is not the way in which I am using 9 the term "economic value" or "worth" or 10 "worthlessness" in my report. 11 BY MR. GOLDBERG: 12 Q If a patient is -- strike that. 13 So if consumers received that economic 14 value that you just described from their treatment 15 of valsartan, is, in your view, the product still 16 worthless? 17 MR. HONIK: Object to form, asked and 18 answered, beyond the scope. 19 THE WITNESS: Okay. So from the 20 Food and Drug Administration's perspective, 21 there are two values associated with a drug -- 22 associated with a prescription drug. One is 23 related to the economic value. Is this product 24 actually available to be sold into the U.S. 25 market? Does supply meet demand?</p>

RESTRICTED CONFIDENTIAL

Page 146	Page 148
<p>1 There is a separate value that is</p> <p>2 related to its therapeutic benefit. Only</p> <p>3 products that are considered to be legitimate</p> <p>4 products, they meet the evidentiary standard</p> <p>5 for sale in the U.S., could have therapeutic</p> <p>6 value, because you need to meet the evidentiary</p> <p>7 standard of being actually allowed on the</p> <p>8 market to be sold before you can have -- be</p> <p>9 judged to have additional therapeutic --</p> <p>10 therapeutic value because it only -- the only</p> <p>11 way that you would know whether that product</p> <p>12 has benefit is if -- for a given patient, is if</p> <p>13 the product meets the evidentiary standard.</p> <p>14 So in my analysis, that -- a product</p> <p>15 has value, economic value, if it meets the</p> <p>16 first part, that is there is a legitimate</p> <p>17 supply curve. Therapeutic value, whether that</p> <p>18 product is -- provides value or clinical value</p> <p>19 or maybe does have some economic value to a</p> <p>20 consumer is all predicated on it meeting --</p> <p>21 COURT REPORTER: Is all predicated...</p> <p>22 THE WITNESS: That goes above and</p> <p>23 beyond the economic value that I have been</p> <p>24 asked to consider.</p> <p>25 I'm sorry. Is there a question? I'm</p>	<p>1 potential downside costs are all predicated on</p> <p>2 the product being a legitimate product allowed</p> <p>3 for sale --</p> <p>4 BY MR. GOLDBERG:</p> <p>5 Q Of a product --</p> <p>6 A Hold on, please, let me finish.</p> <p>7 Allowed for sale in the U.S. market.</p> <p>8 I was asked to assume these -- these products were</p> <p>9 not legitimate products. They were not allowed into</p> <p>10 the U.S. market -- or they were not -- did not meet</p> <p>11 the evidentiary standard for sale. And therefore,</p> <p>12 that clinical value that they may have provided, is</p> <p>13 a separate matter.</p> <p>14 Q That clinical value --</p> <p>15 A Hold on. Hold on.</p> <p>16 And not one that I evaluated. It's</p> <p>17 outside the scope of my report.</p> <p>18 Q That clinical value is meaningless to</p> <p>19 you?</p> <p>20 MR. HONIK: Object to the form, asked</p> <p>21 and answered.</p> <p>22 THE WITNESS: Okay. Again, as, like,</p> <p>23 a human being, obviously, pharmaceutical</p> <p>24 products that are available for sale in the</p> <p>25 U.S. have -- may have clinical value to</p>
Page 147	Page 149
<p>1 hearing voices.</p> <p>2 MR. HONIK: You're hearing background</p> <p>3 noise.</p> <p>4 THE WITNESS: Okay. Okay.</p> <p>5 BY MR. GOLDBERG:</p> <p>6 Q Have you reviewed -- strike that.</p> <p>7 You haven't reviewed any of the</p> <p>8 deposition testimony of any of the plaintiffs or</p> <p>9 class representatives in this case, correct?</p> <p>10 MR. HONIK: Objection, asked and</p> <p>11 answered.</p> <p>12 THE WITNESS: I think you asked that</p> <p>13 question to me this morning, and the answer --</p> <p>14 my answer remains no.</p> <p>15 BY MR. GOLDBERG:</p> <p>16 Q Okay. So you're not aware of the</p> <p>17 plaintiffs and class representatives who have</p> <p>18 testified that they got therapeutic benefits from</p> <p>19 the at-issue valsartan they took? You're not aware</p> <p>20 of that testimony, right?</p> <p>21 MR. HONIK: Object to the form, asked</p> <p>22 and answered, beyond the scope.</p> <p>23 THE WITNESS: Again, it's of no moment</p> <p>24 for my assignment in this case. Therapeutic</p> <p>25 value associated with a product's benefits and</p>	<p>1 individual patients.</p> <p>2 But for the purposes of my report, I'm</p> <p>3 using the term "economic value" in a very</p> <p>4 specific way, which is that the products meet</p> <p>5 the evidence -- either meet the evidentiary</p> <p>6 standard for being allowed to be sold into the</p> <p>7 U.S., or they don't.</p> <p>8 I was asked to assume that they do</p> <p>9 not. And therefore, all the downstream</p> <p>10 potential benefits and costs associated with</p> <p>11 the products are of no moment -- excuse me --</p> <p>12 are of no moment to me.</p> <p>13 BY MR. GOLDBERG:</p> <p>14 Q Let's look at it just from a human</p> <p>15 way, the human standpoint.</p> <p>16 You agree that from a human</p> <p>17 standpoint, consumers who took valsartan between</p> <p>18 2012 and 2018 may have had a therapeutic benefit</p> <p>19 from the drug, right?</p> <p>20 MR. HONIK: Object to the form.</p> <p>21 BY MR. GOLDBERG:</p> <p>22 Q Human standpoint? Not -- not --</p> <p>23 MR. HONIK: Object to the form.</p> <p>24 THE WITNESS: I'm not a doctor, sir.</p> <p>25 I'm so sorry, Ruben.</p>

38 (Pages 146 - 149)

RESTRICTED CONFIDENTIAL

Page 150	Page 152
<p>1 MR. HONIK: That's okay. I think 2 Jamie got it. 3 THE COURT REPORTER: I have not heard 4 anything clearly for the last 10 seconds. 5 MR. HONIK: Okay. Do you want to ask 6 that question again? 7 MR. GOLDBERG: We can strike that 8 question. 9 THE COURT REPORTER: I have -- 10 MR. HONIK: It's stricken, Jamie. 11 COURT REPORTER: Can we go off the 12 record for a second, please? 13 THE VIDEOGRAPHER: The time is 2:44. 14 We're going off the record. 15 (Whereupon, a short break was taken.) 16 THE VIDEOGRAPHER: The time is 2:55. 17 We're back on the record. 18 BY MR. GOLDBERG: 19 Q Dr. Conti, you'd agree that the 20 therapeutic benefits that consumers may have gotten 21 from valsartan between 2012 and 2018 would be 22 different from one consumer to the next, right? 23 MR. HONIK: Object to form, outside 24 the scope. 25 You can answer.</p>	<p>1 Paragraph 42, I state, "Federal law establishes 2 that non-safety and quality compliant 3 adulterated and misbranded prescription drugs 4 are not legitimate consumer products and cannot 5 be lawfully or" -- "lawfully sold or 6 distributed for sale." 7 It is in that context that I am 8 discussing the economic worth or value of the 9 at-issue products. 10 Whether or not an individual consumer, 11 or there were consumers that may have -- 12 COURT REPORTER: Let me just -- excuse 13 me. Sorry. Let me just mute my microphone. 14 MR. HONIK: Go ahead. Go ahead. 15 THE WITNESS: Thank you. So the 16 economic value that I -- let me just start from 17 the beginning. Sorry, Jamie. 18 From my perspective, the economic 19 value that is at issue in my report, in my 20 opinions in this matter, are related to the 21 product -- to the products being either meeting 22 the evidentiary standard for sale or not. 23 Whether or not individual people -- 24 there's a demand curve for these products, and 25 individual people within that demand curve --</p>
Page 151	Page 153
<p>1 THE WITNESS: Again, it's -- it's no 2 moment to my report -- or to my opinions in 3 this matter. 4 BY MR. GOLDBERG: 5 Q I -- I understand. I understand your 6 view. But you've talked about the drug as being 7 worthless, and we're talking about the therapeutic 8 benefit of the drug and -- in the context of your 9 opinion related to worthlessness. 10 My question is, you would agree that 11 consumers would experience the therapeutic benefits 12 from the at-issue valsartan products differently 13 from consumer to consumer? 14 COURT REPORTER: Differently from 15 consumers... 16 MR. GOLDBERG: Differently from 17 consumer to consumer. 18 MR. HONIK: Object to form, asked and 19 answered and beyond the scope of her report. 20 THE WITNESS: Okay. So I think that 21 we are misunderstanding. I think you are 22 misunderstanding the way in which I'm using the 23 term "economic value" or "economic worth." 24 And so maybe if you would indulge me, 25 I can just go back to my report. On page -- on</p>	<p>1 or that make up that demand curve, experience 2 therapeutic benefit or -- benefit or not, is of 3 no moment to my opinion. 4 BY MR. GOLDBERG: 5 Q Is there -- is there some other 6 economic value that you're excluding from your 7 opinion that may have resulted from consumers taking 8 the at-issue valsartan? 9 MR. HONIK: Object to the form. 10 THE WITNESS: I am using the term 11 "economic value" in my report in the way in 12 which I've justified, multiple times, and in 13 the way that the judge in this case has defined 14 "economic value" and its converse, "economic 15 worthlessness." 16 BY MR. GOLDBERG: 17 Q How do you understand the judge in 18 this case has defined "economic value"? 19 A I think it would be easier if I just 20 read from my phone. I have his opinion in front of 21 me. He says -- 22 COURT REPORTER: Please just read 23 slowly and clearly. 24 THE WITNESS: "This Court finds that 25 contaminated drugs are economically worthless</p>

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<p style="text-align: right;">Page 154</p> <p>1 at the point of sale by virtue of the</p> <p>2 dangerousness caused by their contamination,</p> <p>3 regardless whether the sold VCDs actually</p> <p>4 achieve the medical purpose of lowering blood</p> <p>5 pressure." I can go on.</p> <p>6 "Put differently, contaminated drugs,</p> <p>7 even if medically efficacious for their</p> <p>8 purpose, cannot create a benefit of the bargain</p> <p>9 because the contaminants, and their dangerous</p> <p>10 effects, were never bargained for.</p> <p>11 "Further, contaminated drugs do create</p> <p>12 a present injury because their sale should</p> <p>13 never have occurred."</p> <p>14 THE COURT REPORTER: Doctor, just for</p> <p>15 my clarification, what were you reading from?</p> <p>16 THE WITNESS: I was reading from my</p> <p>17 cell phone.</p> <p>18 BY MR. GOLDBERG:</p> <p>19 Q And what were you -- what were you</p> <p>20 reading from?</p> <p>21 A I was reading from an opinion of the</p> <p>22 court.</p> <p>23 Q And who sent you that opinion?</p> <p>24 MR. HONIK: Without waiving -- excuse</p> <p>25 me, without waiving the objection, I'll permit</p>	<p style="text-align: right;">Page 156</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q And did John -- so we talked about the</p> <p>3 therapeutic benefits that may have -- that -- that</p> <p>4 consumers who took the at-issue valsartan products</p> <p>5 may have experienced. You don't dispute that</p> <p>6 consumers who took valsartan at-issue products may</p> <p>7 have experienced therapeutic benefits?</p> <p>8 MR. HONIK: Object to the form, asked</p> <p>9 and answered, beyond the scope.</p> <p>10 You may answer.</p> <p>11 THE WITNESS: Again, the demand curve</p> <p>12 for these products may exist. From an economic</p> <p>13 theory perspective, the demand curve represents</p> <p>14 individual assessments of benefits and costs of</p> <p>15 prescription drugs. I am not disputing that</p> <p>16 there may have been a demand curve for these</p> <p>17 products. That is not my opinion.</p> <p>18 My opinion is related to the supply</p> <p>19 curve. In other words, that products that do</p> <p>20 not meet the evidentiary standard are not</p> <p>21 allowed into the U.S. products of trade, they</p> <p>22 are not viewed as being legitimate products.</p> <p>23 From my perspective, those products are</p> <p>24 worthless.</p> <p>25</p>
<p style="text-align: right;">Page 155</p> <p>1 her to answer.</p> <p>2 THE WITNESS: So I have been aware of</p> <p>3 this opinion for a while, and the opinion was</p> <p>4 provided to me by counsel.</p> <p>5 BY MR. GOLDBERG:</p> <p>6 Q When was that?</p> <p>7 A When did they -- when did I receive</p> <p>8 this via text on my phone?</p> <p>9 Q Yes.</p> <p>10 A Five minutes ago. But I have been</p> <p>11 aware of this before then.</p> <p>12 Q So counsel texted you five minutes ago</p> <p>13 with the judge's opinion that you just read into the</p> <p>14 record?</p> <p>15 MR. HONIK: Without waiving -- excuse</p> <p>16 me, without waiving the objection and</p> <p>17 privilege, I'll permit her to answer.</p> <p>18 THE WITNESS: Yes. It was just texted</p> <p>19 to me. But again, I have been aware of this</p> <p>20 opinion for a while.</p> <p>21 BY MR. GOLDBERG:</p> <p>22 Q And which counsel texted that to you?</p> <p>23 MR. HONIK: Without waiving the</p> <p>24 objection, I'll permit her to answer.</p> <p>25 THE WITNESS: John Davis.</p>	<p style="text-align: right;">Page 157</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q Yeah. And the consumers in that</p> <p>3 demand curve, as you have put it, those -- each</p> <p>4 consumer has -- has their own individual demand for</p> <p>5 the drug, right?</p> <p>6 MR. HONIK: Object -- object to the</p> <p>7 form, asked and answered and beyond the scope.</p> <p>8 You may answer.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. GOLDBERG:</p> <p>11 Q And --</p> <p>12 A I mean, predicated, of course, on</p> <p>13 their doctor being willing to write a prescription</p> <p>14 and their insurer being willing to -- to insure that</p> <p>15 prescription, which is also predicated on FDA</p> <p>16 approval of the product.</p> <p>17 But -- I mean, consumer demand does</p> <p>18 not live in a vacuum outside of physician</p> <p>19 prescribing behavior in this context.</p> <p>20 Q And that physician prescribing</p> <p>21 behavior and the consumer demand for the at-issue</p> <p>22 valsartan products, that's individual from one</p> <p>23 consumer to the next. Why I need the drug is</p> <p>24 different from why someone else might need the drug,</p> <p>25 and so on, right?</p>

RESTRICTED CONFIDENTIAL

Page 158	Page 160
<p>1 MR. HONIK: Object to the form, 2 outside the scope, asked and answered, improper 3 hypothetical. 4 You may answer. 5 THE WITNESS: I don't know what you 6 mean by the term "need," sir. 7 BY MR. GOLDBERG: 8 Q Why I might be prescribed valsartan 9 would likely be different than why someone else 10 might be prescribed valsartan, and these are really 11 individualized issues? 12 MR. HONIK: Same objection as 13 previously stated. 14 THE WITNESS: I mean, that is not 15 consistent with my understanding of demand for 16 prescription drugs. I'm sorry. 17 BY MR. GOLDBERG: 18 Q Do you agree that therapeutic benefits 19 that consumers who have taken at-issue valsartan may 20 have been different from consumer to consumer? 21 MR. HONIK: Object to the form, asked 22 and answered, beyond the scope. 23 THE WITNESS: Again, demand for 24 prescription drugs is related, generally, to 25 their benefits and their costs, predicated on</p>	<p>1 consumer? 2 MR. HONIK: Objection, asked and 3 answered, beyond the scope. I think you've 4 asked her this four times already. 5 THE WITNESS: They may have received 6 exactly the same therapeutic benefit. 7 BY MR. GOLDBERG: 8 Q And they may not, right? 9 A You're -- I'm sorry, sir, but this is 10 impossible. You just interrupted me again, 11 mid-answer, to the same question. 12 Q Go ahead. 13 A No. Please answer your -- please ask 14 your question again, and then I'll answer it. 15 Q Yes or no, do you agree that the 16 therapeutic benefits that consumers may have 17 realized from taking the at-issue valsartan products 18 would have differed from consumer to consumer? 19 MR. HONIK: Same objection. 20 THE WITNESS: Again, this is not a 21 yes-or-no-type question. Consumers may have 22 received exactly the same benefit from at-issue 23 valsartan products, or they may have received 24 different experiences of that product. It is 25 of no moment in my opinions in this matter</p>
Page 159	Page 161
<p>1 the supply of those products being legitimate. 2 In other words, the manufacturer actually 3 meeting the evidentiary standard. 4 BY MR. GOLDBERG: 5 Q Yes or no -- yes or no, do you agree 6 the therapeutic benefit -- 7 A Sir -- 8 Q I thought you were finished with your 9 answer. 10 MR. HONIK: She's not. 11 THE WITNESS: I'm not. I'm not. 12 BY MR. GOLDBERG: 13 Q Why don't you go ahead and finish your 14 answer, and then I'll ask my next question. 15 A Why don't ask you your question again 16 because you interrupted me in mid-answer. 17 Q Oh, okay. 18 A Yeah. 19 Q Yes or no, do you agree that the 20 therapeutic benefits that consumers who have 21 taken -- let me -- let me rephrase. 22 Yes or no, do you agree -- yes or no, 23 do you agree that the consumers who took at-issue 24 valsartan would have received -- would have received 25 different therapeutic benefits from consumer to</p>	<p>1 because, again, demand -- their demand is 2 predicated on a legitimate supply curve. And 3 I've been asked to assume that there was no 4 legitimate supply curve. 5 BY MR. GOLDBERG: 6 Q You would agree, Dr. Conti, that we 7 all have different risk tolerances for things we're 8 willing to put into our bodies? 9 MR. HONIK: Same objection as 10 previously, beyond the scope. 11 THE WITNESS: From the U.S. 12 regulator's perspective, risk tolerance is of 13 no moment. Again, only products that meet the 14 evidentiary standard are allowed to enter into 15 the prescription class of trade in the 16 United States. 17 BY MR. GOLDBERG: 18 Q I'm asking you a different question. 19 Answer my question. 20 You'd agree that people have different 21 risk tolerances from what they're willing to put 22 into their bodies from person to person? 23 MR. HONIK: Same objection as 24 previously. 25 THE WITNESS: Okay. I'm going to</p>

41 (Pages 158 - 161)

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 162</p> <p>1 answer your question again, which is, it is of</p> <p>2 no moment whether people want to consume</p> <p>3 illegitimate products. If there is no</p> <p>4 legitimate supply curve, those products cannot</p> <p>5 enter into the U.S. class of trade. That</p> <p>6 is -- that is the position of the U.S.</p> <p>7 government. And it's --</p> <p>8 BY MR. GOLDBERG:</p> <p>9 Q Is my answer, no, you --</p> <p>10 A Hold on. Hold on.</p> <p>11 Q You're still going?</p> <p>12 A I am still going.</p> <p>13 Q Okay. I mean, I would just say,</p> <p>14 Dr. Conti, I don't mean to be rude. But what</p> <p>15 happens is you -- you kind of -- the way you do this</p> <p>16 is you sort of get to the end of something. It</p> <p>17 seems like you're stopping, and then that's why I'm</p> <p>18 starting. I'm not trying to interrupt you. And</p> <p>19 then you --</p> <p>20 A Mr. Goldberg, that is not the case.</p> <p>21 You just continue to talk over me. The mansplaining</p> <p>22 is a little bit challenging, frankly. But I'll try</p> <p>23 to do this again.</p> <p>24 Q Okay.</p> <p>25 A Again, Americans have a variation of</p>	<p style="text-align: right;">Page 164</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q Your methodology does not take into</p> <p>3 consideration how consumers might have perceived the</p> <p>4 value of the at-issue valsartan to them, correct?</p> <p>5 MR. HONIK: Object to the form.</p> <p>6 THE WITNESS: My analysis presumes</p> <p>7 there is a demand curve for these products.</p> <p>8 What my analysis also presumes is that there is</p> <p>9 no legitimate supply curve for products that do</p> <p>10 not meet the evidentiary standard of the U.S.</p> <p>11 BY MR. GOLDBERG:</p> <p>12 Q What your analysis does not take into</p> <p>13 consideration is whether any consumer perceived that</p> <p>14 they received a therapeutic benefit that provided a</p> <p>15 value to them, right?</p> <p>16 MR. HONIK: Object to the form, asked</p> <p>17 and answered.</p> <p>18 You may answer.</p> <p>19 THE WITNESS: Again, of course, it</p> <p>20 does. There is a demand curve for these</p> <p>21 products. That is not -- that is not the issue</p> <p>22 in this case. Of course, there's a demand</p> <p>23 curve, and I -- I describe it in my report.</p> <p>24 What my report is trying to explain is that</p> <p>25 there is no legitimate supply curve for</p>
<p style="text-align: right;">Page 163</p> <p>1 their risk tolerance. That is of no moment for the</p> <p>2 legitimate class of trade for prescription drugs.</p> <p>3 If the product -- if pharmaceutical companies want</p> <p>4 to sell their products in the U.S., they must meet</p> <p>5 the evidentiary standard. Full stop.</p> <p>6 Q You would agree that some consumers</p> <p>7 would be willing to accept a very low risk of a</p> <p>8 probable human carcinogen, whereas other consumers</p> <p>9 might not be willing to accept the risk of a</p> <p>10 probable human carcinogen?</p> <p>11 MR. HONIK: Object to form, outside</p> <p>12 the scope.</p> <p>13 THE WITNESS: It is of no moment in my</p> <p>14 opinions in this matter. The bottom line is</p> <p>15 that these manufacturers attested to that there</p> <p>16 was no contamination of these products by known</p> <p>17 human carcinogens.</p> <p>18 BY MR. GOLDBERG:</p> <p>19 Q Is the answer to my question, no, you</p> <p>20 don't agree?</p> <p>21 MR. HONIK: Object to the form, asked</p> <p>22 and answered.</p> <p>23 THE WITNESS: I have answered your</p> <p>24 question, sir, the best way that I know how.</p> <p>25</p>	<p style="text-align: right;">Page 165</p> <p>1 products that do not meet the evidentiary</p> <p>2 standard of the U.S. government.</p> <p>3 I was asked to assume that</p> <p>4 products -- that these products at issue</p> <p>5 between 2012 and 2018 did not meet the</p> <p>6 evidentiary standard. They were adulterated</p> <p>7 and misbranded. Therefore, there was no supply</p> <p>8 curve, in my analysis.</p> <p>9 BY MR. GOLDBERG:</p> <p>10 Q Are you familiar with what the FDA</p> <p>11 advised patients to do when the recalls were</p> <p>12 announced?</p> <p>13 MR. HONIK: Object to the form,</p> <p>14 outside the scope.</p> <p>15 THE WITNESS: Specifically, what do</p> <p>16 you mean?</p> <p>17 BY MR. GOLDBERG:</p> <p>18 Q Are you aware that the FDA advised</p> <p>19 people that they should not discontinue their use of</p> <p>20 valsartan until they spoke with their doctor about</p> <p>21 it?</p> <p>22 MR. HONIK: Object to the form, asked</p> <p>23 and answered, outside the scope.</p> <p>24 THE WITNESS: Again, my understanding</p> <p>25 is that there were multiple FDA communications</p>

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Page 166	Page 168
<p>1 when the contamination of these products and 2 their adulteration became known. Is there a 3 specific communication that you are referring 4 to? 5 BY MR. GOLDBERG: 6 Q Well, I think my first question 7 is -- and you can answer no if it's no. 8 Are you aware of the FDA telling 9 patients they should not discontinue the use of 10 their valsartan when the FDA announced the recalls? 11 MR. HONIK: Same objection as 12 previously stated. 13 THE WITNESS: Okay. The FDA had 14 multiple communications with consumers and 15 other suppliers about these products. I'm 16 asking you to be specific. 17 BY MR. GOLDBERG: 18 Q Do you want to turn to Tab 2 in your 19 binder? 20 A Which binder? 21 Q Tab 2 is binder -- that would be 22 binder, I guess, Volume 1 of 3? 23 THE COURT REPORTER: Will this be a 24 new exhibit? 25 MR. GOLDBERG: Yeah -- we'll mark this</p>	<p>1 Q It's probably -- 2 MR. GOLDBERG: For the tech -- it's 3 almost three pages to the end. It's the last 4 three pages-- three pages from the end. 5 THE WITNESS: Do you mean the one that 6 says July 13th, 2018? 7 BY MR. GOLDBERG: 8 Q No, it's -- it's a page before it. 9 It's the page before that. 10 A So that's three pages in. So four 11 pages in, on July 18th, 2018, not the other -- 12 Q Right. 13 A Okay. 14 Q Okay. And at the top of this page, it 15 says -- where it says, "7-18-2018," do you see that? 16 A Yes. 17 Q And this page is referring to the 18 recall of valsartan by ZHP. Do you see that? 19 A I don't see ZHP here. 20 Q Yeah. It's right in the second 21 paragraph. 22 A You mean Zhejiang Huahai 23 Pharmaceuticals? 24 Q Correct. Correct. 25 A Okay. So, yes, I see that here.</p>
Page 167	Page 169
<p>1 as Conti 6. This is a -- 2 (Whereupon, Exhibit Conti 6 was marked 3 for Identification.) 4 BY MR. GOLDBERG: 5 Q Dr. Conti, I'm marking as exhibit 6 Conti 6, a document entitled, "FDA Updates and Press 7 Announcements on Angiotensin II Receptor Blocker 8 Recalls." Do you see that? 9 MR. HONIK: Seth, what's Conti 5? 10 MR. GOLDBERG: Her expert report. 11 MR. HONIK: Thank you. 12 BY MR. GOLDBERG: 13 Q Are you familiar with this document, 14 Dr. Conti? 15 A I am aware of this document. 16 Q This is a document that was cited in 17 your report, right? 18 A There are many documents from the FDA 19 documented -- sorry, cited in my report. 20 Q And this is one of those documents, 21 right? 22 A I don't -- I don't recall. 23 Q If you turn to the very end of this 24 document, it's the July 18th, 2018 statement. 25 A I don't see that, sir. I'm sorry.</p>	<p>1 Q Okay. And at the bottom of that page, 2 there are two bullet points at the very bottom. Do 3 you see those? And -- 4 A Is that a question? 5 Q The first bullet point -- 6 A Is that a question? 7 Q The first bullet point -- the first 8 bullet point, the FDA is instructing patients taking 9 at-issue valsartan that they should continue taking 10 their current medicine until their doctor or 11 pharmacist provides a replacement or a different 12 treatment option. Did I read that correctly? 13 A I think you asked me two questions, 14 but I see that you have read that -- that text 15 correctly. 16 Q Did you consider at all in your 17 assessment the FDA's instructing patients to 18 continue -- to continue taking their medicine until 19 they found an alternative? 20 MR. HONIK: Object to form, asked and 21 answered, beyond the scope. 22 THE WITNESS: Again, from my 23 perspective, there is a demand for these 24 products. In my report, I was asked to assume 25 that these products were contaminated,</p>

RESTRICTED CONFIDENTIAL

Page 170	Page 172
<p>1 adulterated and misbranded. And therefore, 2 there is no -- 3 THE COURT REPORTER: I'm sorry. There 4 is no... 5 THE WITNESS: There is no legitimate 6 supply curve. The fact that the FDA reaffirms 7 that there is a demand curve for these products 8 and many other products that might treat 9 someone's hypertension, is in my report. It 10 is, by definition, considered. 11 My report is about the supply of these 12 products. 13 BY MR. GOLDBERG: 14 Q The FDA is acknowledging that the 15 at-issue valsartan may be providing a therapeutic 16 benefit to the consumers who are taking it, right? 17 MR. HONIK: Object to the form, asked 18 and answered, beyond the scope. 19 THE WITNESS: That's not what it says 20 here on this -- on this document, sir. 21 MR. GOLDBERG: You can take down that 22 document. 23 BY MR. GOLDBERG: 24 Q You're aware that there have been a 25 number of recalls of valsartan since that one in</p>	<p>1 Novartis. 2 There were also many other treatments 3 available for hypertension. I -- I haven't 4 studied all of these FDA communications 5 regarding all of the valsartan products, but my 6 understanding is that the FDA has said to 7 patients that they should discuss with their 8 doctor continuing on the contaminated products 9 and consider the use of non-contaminated or 10 non-adulterated products for their treatment, 11 which included valsartan, specifically the 12 valsartan that were not contaminated or 13 adulterated, but many other products as well. 14 BY MR. GOLDBERG: 15 Q And it also included the valsartan at 16 issue, right, that the FDA was saying, don't 17 discontinue your use of at-issue valsartan, to use 18 your phrase "at-issue," until you talked with your 19 doctor, right? 20 MR. HONIK: Object to the form, beyond 21 the scope. 22 THE WITNESS: No. For example, in the 23 document that we were just talking about, the 24 FDA says -- the "FDA reminds consumers to 25 continue taking your current medication until</p>
Page 171	Page 173
<p>1 July of 2018 that -- that went through July -- went 2 through 2019, right? 3 A I am aware, as I stated earlier, that 4 the FDA has had many communications with the 5 manufacturers about these products and also the 6 American public about these products over -- over 7 time. 8 Q And in each of those recalls, the FDA 9 made the same directive to consumers, that they 10 should not discontinue their use of valsartan until 11 they spoke with their doctor about an alternative? 12 MR. HONIK: Object to form. 13 BY MR. GOLDBERG: 14 Q Is it your testimony that the FDA saw 15 no therapeutic benefit in the at-issue valsartan? 16 MR. HONIK: Object to form, asked and 17 answered, beyond the scope. 18 THE WITNESS: So there were valsartan 19 products that were not contaminated or 20 adulterated or misbranded that were available 21 during this time period, most notably by the 22 manufacturer -- 23 THE COURT REPORTER: I'm sorry. By 24 the manufacturer... 25 THE WITNESS: By the manufacturer</p>	<p>1 you -- until your doctor or pharmacist gives 2 you a replacement or a different treatment 3 option." 4 That is my understanding of what the 5 FDA does, generally, when there are -- there 6 are concerns about the quality of the product, 7 and that is my understanding that that is what 8 happened here. 9 BY MR. GOLDBERG: 10 Q And the products the FDA is referring 11 to in that sentence are the at-issue valsartan 12 products, right? 13 MR. HONIK: Object to form. 14 THE WITNESS: So, actually this -- the 15 statement I just read, but on 7-24-2018, FDA 16 publishes a list of valsartan-containing 17 products not part of the recall. So it's 18 actually talking about products that were not 19 contaminated, adulterated or misbranded. 20 BY MR. GOLDBERG: 21 Q Why don't we go back to the statement 22 we were talking about, which was July 18th, 2018? 23 And that sentence appears -- 24 A You told me -- you told me to put that 25 away. I mean, just the one document, right?</p>

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 174</p> <p>1 So like I said, to begin, when we 2 started this long line of questioning, there were 3 many, many communications the FDA had with American 4 consumers and physicians and pharmacists about 5 valsartan. 6 And so there are many products that 7 are available to treat high blood pressure and 8 hypertension in the U.S. market. We're very 9 fortunate. And the FDA was telling consumers that 10 they should talk to their doctor and talk to their 11 pharmacist about their treatment in the use of both 12 valsartan products, but also many other products 13 that could control their condition as well. 14 Q The directive about the valsartan 15 recall, by the FDA on July 18, 2018, to consumers 16 about the valsartan recall, where the FDA says, 17 "Continue taking your current medicine until your 18 doctor or pharmacist gives you a replacement or a 19 different treatment option," the FDA is saying if 20 you are taking the at-issue valsartan products, you 21 should continue taking those until you talk to your 22 doctor, right? 23 MR. HONIK: Objection to form, asked 24 and answered, beyond the scope. 25 You may answer.</p>	<p style="text-align: right;">Page 176</p> <p>1 that until you speak with your doctor. Okay? 2 MR. HONIK: Object to form, beyond the 3 scope, asked and answered. 4 You may answer. 5 THE WITNESS: Thank you. 6 So, again, there are many valsartan 7 products, and there are valsartan products that 8 don't contain contamination or adulteration. 9 In fact, FDA says that in this specific wording 10 on July 18, 2018. 11 What it's communicating is, to 12 American consumers and their physicians and 13 pharmacists, is that, for those of you taking 14 valsartan products, go talk to your doctor 15 about continuing taking those products or 16 switching. 17 BY MR. GOLDBERG: 18 Q Yeah. Okay. And so if those products 19 are some of the products that are at-issue now, you 20 don't deny that the FDA was saying keep taking them? 21 MR. HONIK: Object to the form, asked 22 and answered. 23 THE WITNESS: You mean the 24 non-recalled products? 25</p>
<p style="text-align: right;">Page 175</p> <p>1 THE WITNESS: Thank you. 2 So, again, just going back to your 3 specifically directed text, the FDA states, 4 "Valsartan is used to treat high blood pressure 5 and heart failure. Not all products containing 6 valsartan" -- "valsartan are recalled, and this 7 update will clarify which valsartan-containing 8 products are being recalled." 9 It then goes on to say there are three 10 current voluntary recalls, which involve Teva 11 products, Princeton products and some other. 12 And then they go on to say you should continue 13 taking your current medication until you talk 14 to your doctor about the treatment of your 15 condition, where your doctor can give you a 16 replacement or a different treatment option. 17 And then they go on to say, as you 18 highlighted, "Not all valsartan-containing 19 medications are affected and being recalled." 20 BY MR. GOLDBERG: 21 Q And the current medicine that they're 22 referring to when they're saying "current medicine," 23 could have been the at-issue valsartan products that 24 somebody had in a bottle of pills at their house, 25 right? And that the FDA is saying continue taking</p>	<p style="text-align: right;">Page 177</p> <p>1 BY MR. GOLDBERG: 2 Q No. I mean products that were 3 recalled. But remember, somebody -- okay. On 4 July 2018 -- on July 2018, if somebody had a bottle 5 of valsartan that is part of the at-issue valsartan 6 products that you're talking about, right? They're 7 sitting at home. They've got their bottle of 8 valsartan. It has NDMA in it. Okay? Just assume. 9 Okay? Accept my assumption. It's hypothetical. 10 Okay? 11 Somebody on July 2018, on 12 July 28, 2018, has a bottle of valsartan, that is 13 one of the at-issue products because it has NDMA in 14 it, you would agree that the FDA is instructing that 15 patient to continue to take that drug until they 16 talk to their doctor, right? 17 MR. HONIK: Object to form, object to 18 the hypothetical based upon facts not of 19 evidence, asked and answered. 20 THE WITNESS: So, again, there are 21 many communications the FDA had with American 22 consumers, physicians and pharmacists about 23 these products. In -- in this specific 24 communication, the FDA reminds consumers, 25 pharmacists and physicians, that there are</p>

RESTRICTED CONFIDENTIAL

Page 178

1 valsartan products that are being recalled, and
2 there are valsartan products that are not part
3 of the recall. And it recommends to consumers
4 that they -- they continue taking their
5 product -- these products, and go talk to their
6 doctor about it.
7 BY MR. GOLDBERG:
8 Q And that includes both valsartan that
9 is being recalled and valsartan that may not be
10 recalled, right?
11 MR. HONIK: Object to the form, asked
12 and answered.
13 THE WITNESS: Yes.
14 BY MR. GOLDBERG:
15 Q Awesome.
16 And did you consider this FDA
17 statement in forming your opinion?
18 A Again, I -- in my report, I assume
19 that there is a demand curve for -- for these
20 prescription drugs, including the at-issue products.
21 Q Yes or no, did you consider this
22 specific statement in forming your opinion?
23 MR. HONIK: Objection, asked and
24 answered.
25 THE WITNESS: Sir, I'm sorry. A

Page 179

1 demand curve, by definition, includes that
2 consumers may -- pharmacists and physicians may
3 want to continue using these at-issue products.
4 The issue --
5 BY MR. GOLDBERG:
6 Q Is the answer to my question, yes?
7 MR. HONIK: You're interrupting her.
8 You're interrupting the witness.
9 BY MR. GOLDBERG:
10 Q Is the answer to my question yes?
11 MR. HONIK: Objection, asked and
12 answered. She's answered that question a dozen
13 times already.
14 BY MR. GOLDBERG:
15 Q Did you consider this statement by the
16 FDA in forming your opinion?
17 MR. HONIK: Objection, asked and
18 answered.
19 THE WITNESS: Thank you.
20 Again, my opinion is that there was a
21 demand curve for valsartan products that
22 included the ones that were -- that are
23 at-issue, that are contaminated or adulterated
24 and misbranded, and others as well that were
25 not.

Page 180

1 All this statement is saying is
2 legitimating my presumption, which is there is
3 a demand curve. And the FDA goes on, in later
4 statements, to American consumers, saying there
5 is a demand curve. All that's supporting my
6 position.
7 MR. GOLDBERG: Why don't we take a
8 two-minute break, if we can. Okay?
9 THE VIDEOGRAPHER: The time is 3:37.
10 This ends Media Unit 3. We're going off the
11 record.
12 (Whereupon, a short break was taken.)
13 THE VIDEOGRAPHER: The time is 4:02.
14 This begins Media Unit Number 4. We're back on
15 the record.
16 BY MR. GOLDBERG:
17 Q Dr. Conti, have you received any other
18 text messages from plaintiffs' counsel today during
19 the deposition?
20 MR. HONIK: Without waiver of the
21 privilege it attaches to work product, I'll
22 permit her to answer.
23 THE WITNESS: No.
24 BY MR. GOLDBERG:
25 Q And have any other documents been sent

Page 181

1 to you by email during the day from plaintiffs'
2 counsel?
3 MR. HONIK: Same objection.
4 You may answer.
5 THE WITNESS: I'm a little afraid of
6 my email, but I haven't checked. So I don't
7 know.
8 BY MR. GOLDBERG:
9 Q Okay. You've -- you've talked about
10 legitimate supply curve, and is -- is it your
11 testimony that no -- that there is no price that
12 could be paid where there's no legitimate supply?
13 MR. HONIK: Object to the form.
14 THE WITNESS: I don't understand your
15 question, sir. I'm sorry.
16 BY MR. GOLDBERG:
17 Q Well, if -- thinking about your
18 Figure 2 where there's no supply curve --
19 A Wait a minute. Wait a minute. Hold
20 on. Just let me get my report, so I can reference
21 what you're referring to.
22 Q So Figure 2 of your -- in your report
23 shows "Demand with no Legitimized Supply."
24 That's -- that's how you've titled this figure,
25 right?

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 182</p> <p>1 A That's accurate.</p> <p>2 Q Is there -- is it -- is it your</p> <p>3 testimony that there's -- that no price could be</p> <p>4 paid under a scenario where there's, to use your</p> <p>5 term, "no legitimate" -- "no legitimate supply"?</p> <p>6 A To be honest, it's a matter of</p> <p>7 economic theory. In order for there to be a price,</p> <p>8 there needs to be both demand and supply. What</p> <p>9 we've been talking about for the past, at least,</p> <p>10 hour, seems like more, is that in my model there is</p> <p>11 demand for these products, although demand falls off</p> <p>12 quite dramatically for these products when the</p> <p>13 recalls start.</p> <p>14 But I have been asked to assume that</p> <p>15 the products at issue were adulterated and</p> <p>16 misbranded. Adulterated and misbranded products are</p> <p>17 not allowed in the U.S. supply chain, and therefore,</p> <p>18 there is no supply. And therefore, there is no</p> <p>19 meeting of demand and supply to arrive at a price.</p> <p>20 Q So there is -- is it your testimony</p> <p>21 that there is no price that would -- could be paid</p> <p>22 for a product where there is no legitimate supply?</p> <p>23 MR. HONIK: Object to the form, asked</p> <p>24 and answered.</p> <p>25 THE WITNESS: As a matter of economic</p>	<p style="text-align: right;">Page 184</p> <p>1 A I meant economic value. And I</p> <p>2 corrected myself and said that there's a -- there's</p> <p>3 an economic value, and then there's a therapeutic</p> <p>4 value.</p> <p>5 Q What -- is there something in</p> <p>6 particular that you're thinking about where the FDA</p> <p>7 has said there is an economic value to a drug?</p> <p>8 MR. HONIK: Objection to the form.</p> <p>9 THE WITNESS: Sure. I put it in my --</p> <p>10 in my report. Let me get to the right</p> <p>11 paragraph, and I'll direct you to it.</p> <p>12 Paragraph 26 of my report, "The FDA</p> <p>13 explains the rationale for its central focus on</p> <p>14 protecting consumers from adulterated and</p> <p>15 misbranded drugs on the web page as follows:</p> <p>16 At the turn of the 20th century, there were no</p> <p>17 federal regulations to protect the public from</p> <p>18 dangerous drugs. 'It was a menacing' --</p> <p>19 "'menacing marketplace filled with products,</p> <p>20 such as William Radam's Microbe Killer and</p> <p>21 Benjamin Bye's'" --</p> <p>22 COURT REPORTER: I'm sorry, Doctor. I</p> <p>23 just -- I lost you there a little bit.</p> <p>24 Marketplace filled with products such</p> <p>25 as William...</p>
<p style="text-align: right;">Page 183</p> <p>1 theory, price cannot be arrived at without</p> <p>2 there being both demand and supply. I have</p> <p>3 been asked to assume there is -- these products</p> <p>4 were adulterated and misbranded, and therefore,</p> <p>5 there is no supply that is legitimate for these</p> <p>6 products as -- as a matter of U.S. policy. And</p> <p>7 therefore, there can be no price.</p> <p>8 BY MR. GOLDBERG:</p> <p>9 Q Is -- is -- in your opinion, is price</p> <p>10 the same as value?</p> <p>11 A So according to the FDA alone, there</p> <p>12 is both an economic price and a therapeutic -- well,</p> <p>13 an economic value and a therapeutic value. We've</p> <p>14 also talked about this quite a lot today.</p> <p>15 There might be therapeutic value, in</p> <p>16 other words, that is encapsulated in the demand</p> <p>17 curve. People -- people trade off the benefits and</p> <p>18 costs of products. But there is no supply of</p> <p>19 illegitimate, adulterated and misbranded products in</p> <p>20 my -- in my model. And therefore, there is no</p> <p>21 price.</p> <p>22 BY MR. GOLDBERG:</p> <p>23 Q You said, "According to the FDA alone,</p> <p>24 there is both an economic price and a therapeutic</p> <p>25 value."</p>	<p style="text-align: right;">Page 185</p> <p>1 THE WITNESS: Sure. I'm sorry.</p> <p>2 "'It was a menacing market'" -- so,</p> <p>3 "'It was a menacing marketplace filled with</p> <p>4 products such as William Radam's Microbe Killer</p> <p>5 and Benjamin Bye's Soothing Balmy Oils to cure</p> <p>6 cancer,' said John Swann, Ph.D., a historian at</p> <p>7 the Food and Drug Administration. Products</p> <p>8 like these were, at minimum, remedies that</p> <p>9 picked the pocket of the user." That's what I</p> <p>10 mean by "economic value."</p> <p>11 "But they could also be downright</p> <p>12 harmful." That's what I mean by</p> <p>13 "therapeutically harmful."</p> <p>14 "I emphasize the text" -- "the text in</p> <p>15 italics because the FDA's statement underscores</p> <p>16 the harms from adulterated and misbranded</p> <p>17 products as twofold: First, economic losses</p> <p>18 from purchasing products that are adulterated</p> <p>19 and misbranded and second, the possibility of</p> <p>20 clinical harm from consumption of adulterated</p> <p>21 and misbranded products."</p> <p>22 From my perspective, there are two</p> <p>23 types of value, and therefore, two types of</p> <p>24 usefulness or worthlessness. There is the</p> <p>25 economic value, and then there is a therapeutic</p>

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 186</p> <p>1 value. The economic value, products such as 2 these -- and products that are adulterated and 3 misbranded should never have entered into the 4 U.S. class of trades. That is the position of 5 the U.S. government, that we do not allow 6 products such as these onto the U.S. market. 7 BY MR. GOLDBERG: 8 Q I -- I thought you said that it was 9 the FDA's view that -- that there was no -- that 10 this term "economic value," you had said, "the FDA 11 alone." And then in your last answer, you referred 12 to you having two views of value, economic value and 13 therapeutic value. 14 Are you basing -- are you basing your 15 view of economic value on what the FDA says? 16 MR. HONIK: Object to the form. You 17 may answer. 18 THE WITNESS: My view is both a matter 19 of economic theory; there is demand that does 20 not meet supply, and therefore there is no 21 price. But also, it is predicated, as my 22 understanding of FDA regulation, and also, 23 frankly, regulation that the pharmaceutical 24 industry itself has -- has wanted, which is 25 that there is only the legitimate supply of</p>	<p style="text-align: right;">Page 188</p> <p>1 Q Just in terms of the FDA -- 2 A And -- wait, and -- just so that 3 you're not mischaracterizing me. 4 It's also the pharmaceutical 5 industry's view that they want to be known as 6 producing and entering products into the U.S. and 7 selling products into the U.S. that are legitimate, 8 that do meet the evidentiary standard as 9 distinguished from products that do not. 10 Q Just as you don't want me to interrupt 11 you, I'd appreciate it if you don't interrupt me. 12 A I was just trying to clarify your 13 mischaracterization of my position. 14 Q In your answer, going back, you refer 15 to the economic theory of supply and demand. What 16 economic treatises have you been relying on for the 17 theory that where there's no legitimate supply, 18 there -- there's no possibility for a delivery of 19 price? 20 A That's Economics 101. 21 MR. HONIK: Objection, asked and 22 answered. 23 THE WITNESS: It's Economics 101. 24 MR. HONIK: I think you got your 25 answer, Seth.</p>
<p style="text-align: right;">Page 187</p> <p>1 products that are not adulterated and 2 misbranded into the U.S. market, those that are 3 valuable. 4 BY MR. GOLDBERG: 5 Q Let's talk about the first part -- 6 A Wait. Wait. Wait. Wait. Wait. 7 Hold on. Let me just -- let me just finish. 8 So it is the -- it is the position of 9 the pharmaceutical industry in the United States 10 since at least the '60s, that they have wanted there 11 to be very clear guidance about what is a legitimate 12 product, that meets the evidentiary standards, and 13 what is a not legitimate product that does not. 14 It is their position that they do not 15 want products on the market that are misbranded, 16 adulterated or otherwise contaminated. 17 Q Are you finished? 18 A I am. Thank you for asking. 19 Q So the first part of that question, 20 you said -- or answer, you said, "My view is more 21 the matter of economic theory. There is demand that 22 does not meet supply, and therefore, there is no 23 price." And then you went on to talk about the 24 FDA's view? 25 A Yes.</p>	<p style="text-align: right;">Page 189</p> <p>1 THE WITNESS: Thank you. 2 It is Economics 101. Literally, my 3 high school student was just taught that price 4 is a function of supply and demand. So that 5 is -- that is a familiar concept to anyone who 6 has taken elementary economics. 7 BY MR. GOLDBERG: 8 Q What economic theory are you relying 9 on for the point that where there is a cGMP 10 violation in a drug, there is no legitimate supply? 11 Which economic theory are you relying on? 12 MR. HONIK: Objection, 13 mischaracterizes her previous response. 14 THE WITNESS: Okay. Again, 15 Economics 101. There can be a demand curve for 16 products that have no supply, legitimate 17 supply. If there is no legitimate supply, 18 there is no economic price. That -- that is 19 just -- that is just elementary economics. 20 BY MR. GOLDBERG: 21 Q I'm asking you, what is the economic 22 theory for an adulterated drug equals no legitimate 23 supply? What's the economic theory for that? 24 A Sure. 25 So this is the most highly -- one of</p>

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 190</p> <p>1 the most highly regulated consumer products in 2 the -- in the U.S. marketplace. And it is the U.S. 3 regulator's perspective that products that do not 4 meet the evidentiary standard of cGMP are not 5 considered prescription drugs. 6 And I can point you to the orange book 7 where the FDA makes that statement. In other words, 8 in order for a prescription drug to be sold in the 9 U.S., to enter into the commercial class of trade 10 and be sold in a pharmacy, it must be produced in 11 accordance with the cGMP at minimum and attested to 12 by the manufacturer, and in addition, meet other 13 evidentiary standards for safety and efficacy. 14 That is the position of the U.S. 15 government. 16 Q Would you agree that patients who 17 would not have taken the at-issue valsartan would 18 have -- because it was not supplied, in your view of 19 the world, would not -- would have needed to take 20 another medication to treat their hypertension? 21 MR. HONIK: Objection, beyond the 22 scope. 23 THE WITNESS: So are you saying 24 that -- because I think I'm -- I think what 25 you're asking is, would there be demand for</p>	<p style="text-align: right;">Page 192</p> <p>1 hyper -- high blood pressure or hypertension or 2 prevent sequella. 3 THE COURT REPORTER: Thank you. 4 BY MR. GOLDBERG: 5 Q Would there have been a cost 6 associated with having to take one of those 7 alternative medications or treatments? 8 MR. HONIK: Object to the form, beyond 9 the scope. 10 THE WITNESS: It depends. 11 BY MR. GOLDBERG: 12 Q If someone had to take a different 13 ARB, they might have had to pay for that ARB, right? 14 MR. HONIK: Object to the form. 15 THE WITNESS: They may have. They may 16 have decided to manage their -- their treatment 17 in many other ways. Physicians can choose to 18 do many things. We know that demand for 19 valsartan products that were recalled dropped 20 precipitously, and so those consumers went 21 elsewhere. Where they went, there are many, 22 many options available to them and their 23 physicians. 24 BY MR. GOLDBERG: 25 Q Is it -- your analysis doesn't take</p>
<p style="text-align: right;">Page 191</p> <p>1 treatment of hypertension and high blood 2 pressure regardless of whether these products 3 were on the market? Is that what you're 4 asking? 5 BY MR. GOLDBERG: 6 Q Sure. 7 A Okay. Consumers in America who suffer 8 from high blood pressure or hypertension or other 9 related conditions certainly seek treatment. They 10 demand treatment for those conditions. 11 My understanding, and as I understand 12 it, your own experts have suggested that there were 13 many treatments available for those conditions, 14 including uncontaminated, unadulterated valsartan 15 manufactured by Novartis, among others. And 16 other -- many other products and non-pharmaceutical 17 products -- 18 THE COURT REPORTER: I'm sorry, 19 Doctor, can you repeat the end of that? 20 THE WITNESS: Sure. 21 Where -- so my understanding is that 22 there are many products that are 23 pharmaceutical, in addition to other 24 non-pharmaceutical products, that can treat the 25 underlying conditions to either mitigate the</p>	<p style="text-align: right;">Page 193</p> <p>1 into account the cost that a consumer might have had 2 to pay for a different medication? 3 MR. HONIK: Object to the form. 4 THE WITNESS: Or do you mean or other 5 management techniques? Because there are many 6 management techniques. 7 BY MR. GOLDBERG: 8 Q Sure. 9 A Some which would have cost less. 10 Q Your -- your analysis doesn't take 11 into account any other -- any -- the cost of any 12 alternative treatment of medication, right? 13 MR. HONIK: Object to the form. 14 THE WITNESS: That is outside the 15 scope of my report, sir. 16 BY MR. GOLDBERG: 17 Q Is it possible that if it 18 weren't -- if they hadn't taken the at-issue 19 valsartan products, consumers might have paid more 20 for a hypertension medication? 21 MR. HONIK: Object to the form. 22 THE WITNESS: I've learned in this 23 world anything is possible. I mean, there are 24 many, many ways of controlling high blood 25 pressure and -- and other related conditions</p>

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<p style="text-align: right;">Page 194</p> <p>1 that people may have taken valsartan for during</p> <p>2 this time period. I have no opinion whether or</p> <p>3 not those other therapeutic alternatives,</p> <p>4 including doing nothing, were lostless or</p> <p>5 costly.</p> <p>6 BY MR. GOLDBERG:</p> <p>7 Q Why is the cost of an alternative</p> <p>8 medication not pertinent to your analysis?</p> <p>9 MR. HONIK: Object to the form, asked</p> <p>10 and answered.</p> <p>11 THE WITNESS: Because my damages</p> <p>12 calculation is focused on the injury that</p> <p>13 occurred to consumers and to end-party payors</p> <p>14 for contaminated, adulterated and misbranded</p> <p>15 valsartan products that were recalled during</p> <p>16 the time period. Whether or not people went</p> <p>17 elsewhere, the downstream economic costs to</p> <p>18 that -- to that contamination are of no moment</p> <p>19 in my economic calculation.</p> <p>20 And maybe the way that I like to think</p> <p>21 of it is this way, which is I was asked to</p> <p>22 calculate damages associated with this injury,</p> <p>23 the defendants selling adulterated, misbranded</p> <p>24 products into the U.S. marketplace that</p> <p>25 consumers --</p>	<p style="text-align: right;">Page 196</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q Okay. You said the drug shouldn't be</p> <p>3 sold, and that it was an illegitimate supply, right?</p> <p>4 MR. HONIK: Object to form.</p> <p>5 THE WITNESS: They are not the same</p> <p>6 thing, sir.</p> <p>7 BY MR. GOLDBERG:</p> <p>8 Q Okay. If consumers would have paid</p> <p>9 more for a different drug because</p> <p>10 valsartan -- because the at-issue valsartan were not</p> <p>11 sold, doesn't -- wouldn't that have mattered to your</p> <p>12 analysis?</p> <p>13 MR. HONIK: Object to the form, asked</p> <p>14 and answered, improper hypothetical, facts not</p> <p>15 in evidence.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: Thank you.</p> <p>18 You have asked this question four</p> <p>19 times, and I have already answered it. But I'm</p> <p>20 happy to answer it again.</p> <p>21 Again, injury occurs at the time of</p> <p>22 the accident, at the time of -- at the time of</p> <p>23 the accident. Whether consumers would have</p> <p>24 gone on to buy something else after the injury</p> <p>25 occurred is of no moment. There was an</p>
<p style="text-align: right;">Page 195</p> <p>1 THE COURT REPORTER: That consumers...</p> <p>2 THE WITNESS: And end-payors or</p> <p>3 insurers didn't know about.</p> <p>4 Injury occurs -- in other words, if</p> <p>5 you get hit by a car, injury occurs at the time</p> <p>6 of the car, being hit. If people go elsewhere</p> <p>7 after they hit their -- after their car was</p> <p>8 hit, maybe they buy a new car or it's more</p> <p>9 costly, maybe they go without a car all</p> <p>10 together, that's -- that's not related to my</p> <p>11 calculation. It's of no moment. The</p> <p>12 economic --</p> <p>13 BY MR. GOLDBERG:</p> <p>14 Q You --</p> <p>15 A Hold on. The economic loss occurs at</p> <p>16 the time of injury.</p> <p>17 Q You said that this drug should not</p> <p>18 have been sold to those consumers, right?</p> <p>19 A That's not what I said, sir.</p> <p>20 Q So the drug could have been sold to</p> <p>21 consumers?</p> <p>22 MR. HONIK: Object to form.</p> <p>23 THE WITNESS: That's not what I said</p> <p>24 either, sir.</p> <p>25</p>	<p style="text-align: right;">Page 197</p> <p>1 economic loss. People bought things that</p> <p>2 shouldn't -- they -- that under the assumptions</p> <p>3 that were given to me, Counsel, should not have</p> <p>4 entered into the legitimate class of trade.</p> <p>5 BY MR. GOLDBERG:</p> <p>6 Q Okay. So I just asked you, your</p> <p>7 testimony is that these drugs should not have</p> <p>8 entered into the class of trade, right?</p> <p>9 A No. What I was asked --</p> <p>10 Q And my question is --</p> <p>11 A No. What I was asked to assume is</p> <p>12 that these products were adulterated and misbranded.</p> <p>13 If a product is adulterated and misbranded,</p> <p>14 according to U.S. regulation and pharmaceutical</p> <p>15 manufacturers, they are not allowed to enter into</p> <p>16 the U.S. class of trade. And therefore, there was</p> <p>17 no supply.</p> <p>18 Q Okay.</p> <p>19 A Injury occurs because these</p> <p>20 products -- these contaminated products entered into</p> <p>21 the U.S. class of trade and people bought them. And</p> <p>22 insurers purchased -- insurers paid for them. The</p> <p>23 economic loss arising, therefore, from the purchase</p> <p>24 of products that, under this theory of damages,</p> <p>25 should not have occurred.</p>

50 (Pages 194 - 197)

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Page 198

1 What people would have done after the
2 injury, they switched products to another
3 prescription drug, they managed their hypertension
4 by diet and exercise, they underwent stent therapy,
5 all of those other things are of no moment to my
6 assessment of economic loss.
7 BY MR. GOLDBERG:
8 Q I'm not talking about after the injury
9 at this point. I'm talking about instead of the
10 injury. Instead of buying the at-issue valsartan
11 because it was not on the market and a consumer
12 bought a different ARB or a different drug and paid
13 more for that, that doesn't matter to your -- would
14 have paid more for that, that doesn't matter to your
15 analysis?
16 MR. HONIK: Objection, asked and
17 answered, improper hypothetical.
18 THE WITNESS: So -- I mean, really the
19 alternative here is not -- is that the
20 manufacturers actually sold unadulterated,
21 properly branded product, not that consumers
22 were forced to go elsewhere, in my economic
23 analysis.
24 BY MR. GOLDBERG:
25 Q In an economic analysis where a

Page 199

1 consumer would have taken a different drug instead
2 of the at-issue valsartan, and they would have paid
3 the same or more for that different drug, did the
4 consumer have an economic injury?
5 MR. HONIK: Objection, asked and
6 answered, improper hypothetical.
7 THE WITNESS: From my perspective, if
8 the consumer did not buy adulterated or -- and
9 misbranded, illegitimate valsartan products,
10 they are not injured.
11 So all of those people between 2012
12 and 2018 that took Novartis-brand valsartan
13 that was not recalled or contaminated, they are
14 out of my class. They are out of the -- my
15 calculation of damages.
16 All of those people between 2012 and
17 2018 that used other therapeutic modalities to
18 treat their hypertension are of no moment to
19 me, in my economic analysis.
20 My economic analysis is only focused
21 on the people who purchased adulterated and
22 misbranded valsartan products that were
23 ultimately recalled.
24 BY MR. GOLDBERG:
25 Q And if they didn't make that purchase,

Page 200

1 they would have had to purchase some other drug,
2 right?
3 MR. HONIK: Object to the form. It's
4 been asked and answered, I don't know, 15 times
5 already.
6 THE WITNESS: There are many, many
7 treatments for hypertension and high blood
8 pressure out there. Some of them are
9 pharmaceutical. Some of them are other things.
10 It's immaterial to my perspective. I am simply
11 focused on the people who actually bought or
12 insured the contaminated, misbranded and
13 adulterated products at-issue in this matter.
14 BY MR. GOLDBERG:
15 Q Do you know the difference between
16 compensatory damages and punitive damages?
17 MR. HONIK: Object to the form,
18 outside the scope, calls for an expert legal
19 opinion.
20 THE WITNESS: No. I'm not a lawyer.
21 Maybe in my future life.
22 BY MR. GOLDBERG:
23 Q In your view, the damages you
24 calculated, are you -- are you calculating damages
25 to compensate consumers or their loss or deter

Page 201

1 manufacturers from making drugs that have
2 adulterations or misbranding?
3 MR. HONIK: Same objection to the
4 extent it calls for a legal conclusion.
5 You may answer.
6 THE WITNESS: I'm sorry. I -- I
7 didn't quite follow. Can you slow down and ask
8 not a compound question, but in parts?
9 BY MR. GOLDBERG:
10 Q Turn to Paragraph 45 of your report.
11 A So we're moving on? You're not going
12 to ask that question?
13 Q I'm moving on.
14 A Oh, okay.
15 Q Do you have Paragraph 45 up?
16 A Uh-huh.
17 Q In Paragraph 45, you write, "Assigning
18 a non-zero value to non-safety and quality compliant
19 products is perverse. To do so would be to
20 incentivize and legitimize cheating and
21 noncompliance by manufacturers and other members of
22 the United States pharmaceutical supply chain."
23 Did I read that correctly?
24 A That's what it says.
25 Q Is it your opinion that -- that the

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<p style="text-align: right;">Page 202</p> <p>1 damages you calculated are intended to</p> <p>2 disincentivize manufacturers from cheating and</p> <p>3 noncompliance?</p> <p>4 MR. HONIK: Object to the form.</p> <p>5 BY MR. GOLDBERG:</p> <p>6 Q Well, let me put it another way.</p> <p>7 Are you -- are you suggesting that</p> <p>8 manufacturers should be deterred from cheating and</p> <p>9 noncompliance?</p> <p>10 A It is the U.S. government's position,</p> <p>11 evolving over time, and also pharmaceutical</p> <p>12 manufacturers' position, that the illegitimate,</p> <p>13 misbranded, adulterated, contaminated, criminal</p> <p>14 class of trade of prescription drugs should be</p> <p>15 minimized at, if at all, at all possibilities.</p> <p>16 There's 100 years of focus on reducing</p> <p>17 products that pick the pocket of consumers, don't do</p> <p>18 what they say or could even cause harm. To allow</p> <p>19 those products onto the market to legitimate this</p> <p>20 type of cheating, goes against U.S. policy and,</p> <p>21 frankly, the pharmaceutical industry's position, for</p> <p>22 the better part of many decades.</p> <p>23 BY MR. GOLDBERG:</p> <p>24 Q So in calculating the damages the way</p> <p>25 you have, are you taking into account the need to</p>	<p style="text-align: right;">Page 204</p> <p>1 damages associated with misconduct.</p> <p>2 BY MR. GOLDBERG:</p> <p>3 Q Right. So --</p> <p>4 A Myself -- I mean, from, again, an</p> <p>5 economic perspective, these products are worthless.</p> <p>6 The court has agreed. Consumers and third-party</p> <p>7 payors suffered an economic harm. And my analysis</p> <p>8 calculates that economic harm, which is the full</p> <p>9 price of the product that they paid at the pharmacy</p> <p>10 counter.</p> <p>11 Q Why do you -- why is it necessary for</p> <p>12 you to -- to say that a nonzero value is perverse</p> <p>13 and would incentivize to you? What -- what does</p> <p>14 that have to do with your economic calculation?</p> <p>15 A It goes -- because it goes -- because</p> <p>16 assigning a nonzero value goes against U.S. policy</p> <p>17 and the pharmaceutical companies' own position on</p> <p>18 the matter of illegitimate products for the better</p> <p>19 part of 50 -- and if you count from 1906, the better</p> <p>20 part of more than 100 years of U.S. policy. But,</p> <p>21 again, products that are illegitimate, that do not</p> <p>22 meet cGMP, that would not be allowed to come into</p> <p>23 the U.S. market, they have no economic value. And</p> <p>24 the court agrees with me.</p> <p>25 THE COURT REPORTER: And the -- I'm</p>
<p style="text-align: right;">Page 203</p> <p>1 deter manufacturers from wrongdoing, as you put it?</p> <p>2 MR. HONIK: Object to the form, calls</p> <p>3 for a legal conclusion, beyond the scope of her</p> <p>4 report.</p> <p>5 THE WITNESS: I'm sorry. I don't</p> <p>6 quite understand your question. Can you please</p> <p>7 repeat it?</p> <p>8 BY MR. GOLDBERG:</p> <p>9 Q In calculating -- in calculating the</p> <p>10 damages that you've calculated, are you trying to</p> <p>11 also account for some punishment, if you will, of</p> <p>12 manufacturers -- of the defendants for manufacturing</p> <p>13 drugs that had an impurity in it?</p> <p>14 MR. HONIK: Same objection. She's not</p> <p>15 a lawyer, beyond the scope.</p> <p>16 THE WITNESS: I'm sorry. I don't -- I</p> <p>17 don't quite understand what you mean. Am I</p> <p>18 trying to punish the manufacturers? Is that</p> <p>19 what you're asking?</p> <p>20 BY MR. GOLDBERG:</p> <p>21 Q Yes.</p> <p>22 MR. HONIK: Same objection.</p> <p>23 THE WITNESS: Again, that's no moment</p> <p>24 to my -- that has no moment in my opinions in</p> <p>25 this matter. I was asked to calculate economic</p>	<p style="text-align: right;">Page 205</p> <p>1 sorry.</p> <p>2 THE WITNESS: And the court agrees</p> <p>3 with me on that point.</p> <p>4 COURT REPORTER: Thank you.</p> <p>5 THE WITNESS: Thank you.</p> <p>6 BY MR. GOLDBERG:</p> <p>7 Q I just want to confirm, you have not</p> <p>8 made any attempt to consider whether a consumer</p> <p>9 would have paid a different co-payment for a</p> <p>10 different drug but for their purchase of valsartan?</p> <p>11 MR. HONIK: Object to the form.</p> <p>12 THE WITNESS: I already answered this</p> <p>13 question, sir.</p> <p>14 But, again, all I considered in my</p> <p>15 analysis is what consumers actually paid for</p> <p>16 these at-issue products.</p> <p>17 BY MR. GOLDBERG:</p> <p>18 Q And the same is true for TPPs? All</p> <p>19 you considered for end-payors or third-party payors</p> <p>20 is what they actually paid for the product?</p> <p>21 THE COURT REPORTER: Is what they</p> <p>22 actually...</p> <p>23 MR. GOLDBERG: Paid for the product.</p> <p>24 THE WITNESS: Correct.</p> <p>25</p>

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<p style="text-align: right;">Page 206</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q Just moving on into another area of</p> <p>3 your report --</p> <p>4 THE WITNESS: Excuse me. If we're</p> <p>5 moving on, before there's a question pending,</p> <p>6 do you mind if we take a break, please?</p> <p>7 MR. GOLDBERG: No, that's fine.</p> <p>8 THE VIDEOGRAPHER: The time is 4:41.</p> <p>9 We're going off the record.</p> <p>10 (Whereupon, a short break was taken.)</p> <p>11 THE VIDEOGRAPHER: The time is 4:52.</p> <p>12 This begins Media Unit Number 5. We're back on</p> <p>13 the record.</p> <p>14 BY MR. GOLDBERG:</p> <p>15 Q Dr. Conti, can you turn in your report</p> <p>16 to Paragraph 58?</p> <p>17 A I'm there.</p> <p>18 Q At the beginning of this paragraph,</p> <p>19 you say, "Plaintiffs' counsel have asked me to</p> <p>20 calculate damages for four different theories of</p> <p>21 liability against the manufacturer defendants and</p> <p>22 two different theories of liability and one theory</p> <p>23 of unjust enrichment against the defendant</p> <p>24 retailers."</p> <p>25 Do you see that?</p>	<p style="text-align: right;">Page 208</p> <p>1 Again, the retailers are different. But --</p> <p>2 THE COURT REPORTER: But from the</p> <p>3 defendants...</p> <p>4 MR. HONIK: I think she said the</p> <p>5 retailers are different.</p> <p>6 THE WITNESS: Right. For the</p> <p>7 defendants, the measure of economic liability</p> <p>8 is the same. It's the price that was paid.</p> <p>9 And for the retailers, it's different.</p> <p>10 THE COURT REPORTER: Thank you.</p> <p>11 BY MR. GOLDBERG:</p> <p>12 Q And leaving aside unjust enrichment,</p> <p>13 in what way is -- is it different for the retailers?</p> <p>14 A Let's go down and talk about it.</p> <p>15 So the -- the retailers sold the</p> <p>16 product to consumers, and they obtained their own</p> <p>17 benefit from selling these products. So it's the</p> <p>18 economic loss or economic gain associated with the</p> <p>19 retailers' sale that's different than the</p> <p>20 defendants' sale.</p> <p>21 Q Okay. I'm not going to get into the</p> <p>22 economic damages for the retailers, at this point.</p> <p>23 I'm -- I'm going to leave that for somebody else.</p> <p>24 You have that -- you made that</p> <p>25 statement. I just wanted to clarify that one point.</p>
<p style="text-align: right;">Page 207</p> <p>1 A Yes.</p> <p>2 Q The unjust enrichment damages that you</p> <p>3 calculated, did you apply the same measure of</p> <p>4 damages to all of the different theories of</p> <p>5 liability?</p> <p>6 A They differ by the states included in</p> <p>7 the calculations.</p> <p>8 Q To your knowledge, is that the only</p> <p>9 difference that -- as between these different</p> <p>10 theories of liability?</p> <p>11 A Generally, yes. And then -- I mean,</p> <p>12 in terms of the defendants, the terms of the</p> <p>13 retailers, there's both data and --</p> <p>14 THE COURT REPORTER: And what? And</p> <p>15 what, Doctor?</p> <p>16 THE WITNESS: And states that are</p> <p>17 different from the retailers.</p> <p>18 BY MR. GOLDBERG:</p> <p>19 Q In terms of the measure of damages for</p> <p>20 all of the liability, leaving aside unjust</p> <p>21 enrichment, the measure of damages for all of them</p> <p>22 is the same, which is a full refund of the price</p> <p>23 paid at the point of sale?</p> <p>24 MR. HONIK: Object to the form.</p> <p>25 THE WITNESS: Correct. Yeah, correct.</p>	<p style="text-align: right;">Page 209</p> <p>1 In terms of the -- the manufacturer</p> <p>2 damages, you -- you relied -- you're relying on data</p> <p>3 from IQVIA? Am I correct?</p> <p>4 A Right. I'm relying on national sales</p> <p>5 by product, manufacturer, month, state and payment</p> <p>6 types of who the payor is. And I'm also relying on</p> <p>7 national data related to the co-payment amounts, or</p> <p>8 co-insurance amounts, that consumers paid. Again,</p> <p>9 by product, payor, state, month, year.</p> <p>10 Q And how did you get the data that you</p> <p>11 relied upon?</p> <p>12 A I instructed my staff to purchase the</p> <p>13 data on my behalf.</p> <p>14 THE COURT REPORTER: To purchase?</p> <p>15 THE WITNESS: To purchase, yes.</p> <p>16 BY MR. GOLDBERG:</p> <p>17 Q Did you provide a specific instruction</p> <p>18 as to what -- what parameters you were looking for</p> <p>19 for them to purchase?</p> <p>20 A I think I just made that clear in my</p> <p>21 previous answer, sir.</p> <p>22 I -- I look at IQVIA data every day in</p> <p>23 my research, and they are known as the gold standard</p> <p>24 for pharmaceutical sales of legitimate prescription</p> <p>25 drugs in the U.S. consumer market.</p>

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<p style="text-align: right;">Page 210</p> <p>1 Q Do you know whether there are any</p> <p>2 limitations to the IQVIA data you relied upon or</p> <p>3 purchased?</p> <p>4 A Oh, goodness, Mr. Goldberg, there are</p> <p>5 always limitations, but they are the gold standard.</p> <p>6 They are used by the pharmaceutical industry</p> <p>7 themselves for assessing sales of products both in</p> <p>8 their own market but also in competitor markets.</p> <p>9 And, you know, I am not aware of a product that is</p> <p>10 better.</p> <p>11 Q Do you know that there are some</p> <p>12 sources of data that IQVIA is not able to obtain and</p> <p>13 makes projections in place of the data that they</p> <p>14 can't obtain?</p> <p>15 A So the Xponent data that I used is</p> <p>16 comprised of approximately 92 percent of total</p> <p>17 prescription sales for legitimate consumer</p> <p>18 product -- legitimate pharmaceutical products in the</p> <p>19 U.S. class of trade. There are some holes in their</p> <p>20 audit, but with prescription manufacturers and</p> <p>21 pharmacies. But those are not holes that are</p> <p>22 particularly relevant to these specific products.</p> <p>23 What I mean by that is that we know</p> <p>24 that Xponent data does not have -- does not have</p> <p>25 good purview into drugs that are sold to some</p>	<p style="text-align: right;">Page 212</p> <p>1 data in -- in my report. I've also written -- I've</p> <p>2 used Xponent data for my own research in many, many</p> <p>3 different contexts. And so those limitations for</p> <p>4 this type of data are very well known. They're well</p> <p>5 characterized, and I cite those in my report, the</p> <p>6 fact that Xponent doesn't contain all consumer</p> <p>7 co-insurance.</p> <p>8 THE COURT REPORTER: Co-insurance...</p> <p>9 THE WITNESS: Co-payment amounts that</p> <p>10 consumers pay -- paid for these products is</p> <p>11 accounted for in a specific way in this</p> <p>12 analysis. Specifically, I took average</p> <p>13 insurance and co-payment amounts by product,</p> <p>14 month, year, manufacturer and applied that to</p> <p>15 the analysis --</p> <p>16 THE COURT REPORTER: The analysis...</p> <p>17 THE WITNESS: When appropriate.</p> <p>18 THE COURT REPORTER: One more time.</p> <p>19 THE WITNESS: When appropriate.</p> <p>20 COURT REPORTER: I'm sorry. Thank</p> <p>21 you.</p> <p>22 THE WITNESS: No problem. It's the</p> <p>23 end of a day.</p> <p>24 BY MR. GOLDBERG:</p> <p>25 Q From the IQVIA data, the Xponent data,</p>
<p style="text-align: right;">Page 211</p> <p>1 hospitals in the U.S. and some specialty pharmacies.</p> <p>2 But those are not -- these are</p> <p>3 not -- these products at-issue here are not really</p> <p>4 those drugs. It's largely drugs that are -- that</p> <p>5 are used in the inpatient setting to treat very,</p> <p>6 very sick people in the ICU and -- and otherwise.</p> <p>7 The retail class of trade from regular</p> <p>8 pharmacies like CVS and Walgreens are the -- are the</p> <p>9 products that are at-issue here and that -- in that</p> <p>10 class of trade.</p> <p>11 THE COURT REPORTER: That class of --</p> <p>12 that class of trade...</p> <p>13 THE WITNESS: That is at-issue in this</p> <p>14 math certificate.</p> <p>15 Xponent also doesn't capture all</p> <p>16 co-insurance and co-payment amounts. It</p> <p>17 captures approximately 80 percent that are</p> <p>18 purchased, not all that are purchased or all</p> <p>19 that are paid in the legitimate consumer --</p> <p>20 legitimate pharmaceutical market in the U.S.</p> <p>21 And my methods account for that.</p> <p>22 BY MR. GOLDBERG:</p> <p>23 Q How do your methods account for that?</p> <p>24 How do you explain that?</p> <p>25 A So I explain the limitations of this</p>	<p style="text-align: right;">Page 213</p> <p>1 you -- that data does not identify the specific</p> <p>2 patients who purchased valsartan, right?</p> <p>3 A It's inclusive of all patients that</p> <p>4 purchased valsartan or who prescribed and dispensed</p> <p>5 valsartan by definition.</p> <p>6 Q You can't use that data to identify</p> <p>7 any particular patient, right?</p> <p>8 A Correct, it is inclusive of all.</p> <p>9 Q And you can't use that data to</p> <p>10 identify any particular payor for valsartan?</p> <p>11 A That is -- that is incorrect.</p> <p>12 Q I thought - I thought I just heard you</p> <p>13 say that, so maybe I misheard you.</p> <p>14 A No.</p> <p>15 MR. HONIK: Wait. Wait. Wait for a</p> <p>16 question. Wait for a question.</p> <p>17 MR. GOLDBERG: Okay. I did mishear</p> <p>18 you. You said prescribe and dispense.</p> <p>19 BY MR. GOLDBERG:</p> <p>20 Q Does the IQVIA -- does the IQVIA data</p> <p>21 permit you to determine a particular class member's</p> <p>22 damages in this case?</p> <p>23 A The IQVIA data allows me to</p> <p>24 disaggregate sales of products by product, and by</p> <p>25 payor type.</p>

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<p style="text-align: right;">Page 214</p> <p>1 Q So no, you couldn't get to a 2 particular class member's data in this case through 3 the IQVIA data? 4 A I'm not sure I understand what you 5 mean by "class member." I mean, my -- my -- excuse 6 me. My understanding is that class members are, by 7 definition, defined buy payor type and also by 8 state. 9 Q Did you look at the IQVIA data and 10 determine what a particular consumer paid for 11 valsartan in cash? 12 MR. HONIK: Objection, asked and 13 answered. 14 THE WITNESS: It is inclusive of all 15 payments made by all consumers who are 16 presumable class members, and it's inclusive of 17 all payors that are inclusive of all payor 18 class members by month, state, year and 19 product. 20 BY MR. GOLDBERG: 21 Q Right. It doesn't get -- it doesn't 22 allow you to drill down to what a particular 23 consumer paid -- 24 MR. HONIK: Do you mean without more? 25 Do you mean without more? Is that what you</p>	<p style="text-align: right;">Page 216</p> <p>1 specific payor. There are payor variables that 2 are pretty specific in the IQVIA data that 3 would allow me to characterize or identify 4 payors to a pretty specific degree. 5 BY MR. GOLDBERG: 6 Q What -- what is that specific degree? 7 A So I know where the payor is located, 8 what the payor's type is, and also what the payor's 9 name is for each individual product, month, year, 10 combination. 11 Q And by "payor," you're -- when you're 12 talking about -- you're talking about third-party 13 payors? When you're talking about getting to that 14 level of specificity, you're talking about 15 third-party payors or consumers? 16 A Third-party payors. 17 Q When you calculated average co-pays, 18 did you exclude co-pays -- 0-dollar co-pays in your 19 averaging? 20 MR. HONIK: Object to form. 21 THE WITNESS: I did not. 22 BY MR. GOLDBERG: 23 Q Is it the -- you just mentioned the -- 24 the specificity with respect to TPPs. Is it your 25 view and understanding that all TPPs are advised in</p>
<p style="text-align: right;">Page 215</p> <p>1 mean, Seth? 2 MR. GOLDBERG: The question is 3 pending. I asked her about the Xponent data. 4 MR. HONIK: The problem is you've 5 asked it six times. I think she's answered it 6 as best she can. It's aggregate data is what 7 she's saying, and if you're asking -- 8 MR. GOLDBERG: Are you testifying? 9 MR. HONIK: No. I'm just -- I think 10 you're going round and round. 11 But answer it as best you can. 12 THE WITNESS: Can you restate the 13 question, please? 14 BY MR. GOLDBERG: 15 Q The IQVIA data doesn't allow you to 16 drill down to what a particular class member paid 17 for at-issue valsartan? 18 MR. HONIK: Object to form, asked and 19 answered. 20 THE WITNESS: So, again, IQVIA's data 21 is specific to the product, month, year, payor 22 and state. And therefore -- and across all the 23 U.S. And therefore, it is -- it is -- it 24 contains in it every single potential class 25 member, whether they be a consumer or a</p>	<p style="text-align: right;">Page 217</p> <p>1 the IQVIA data? 2 A Well, the TPPs that I used for my 3 damage calculations met certain criteria. 4 Q What were those criteria? 5 A They're listed in my report. 6 Q Do you want to point to that? 7 A Sure, give me a second. Are you with 8 me? 9 Q Uh-huh. 10 A Okay, great. Page 29 of my report, 11 Paragraph 75, I define end-payor class damages. And 12 in Paragraph 75, I say, "...my calculation of 13 End-Payor Class damages includes three parts. 14 First, I limit both sets of Xponent data" -- both 15 the total national sales but also co-insurance 16 co-payments, they are actually two separate 17 datasets, "to exclude cash paid claims as well as 18 claims paid by the following state and federal 19 government entities (based on plan categories or 20 plan names in the Xponent data):" 21 "CHIP," Children's Health Insurance 22 Program, "federal assistance programs, Medicare 23 Parts A and B...", Medicare Part A is for hospital 24 plans, we were just talking about that before. 25 We're not talking about that class of trade here.</p>

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<p style="text-align: right;">Page 218</p> <p>1 And Medicare Part B, which is the insurance that 2 covers drugs that are infused or injected or 3 otherwise given to patients in a medical office. 4 State insurance programs -- assistance 5 programs, to include ADAP. ADAPs are state 6 assistance programs with people with HIV or other 7 infectious disease. Tricare, a military program -- 8 a military insurance program, department of Veterans 9 Affairs, another -- another military insurance 10 program, the Indian Health Service, state employee 11 plans, which include city and county plans -- sorry. 12 Not -- I didn't exclude city and county plans. And 13 Workers Compensation plans. 14 And you can see there's a note that 15 follows that. This occurs for 464 distinct 16 combinations of manufacturer, product, state and 17 month out of the 36,000ish -- oh, no, I'm sorry. 18 Right. It includes the valsartan class definitions 19 and exclusions. It's -- it's Footnote 17. 20 Q Why -- why did you -- what do you 21 understand your reason for excluding the claims paid 22 by those state and federal government entities? Why 23 did you want to exclude those from your 24 calculations? 25 A That was a --</p>	<p style="text-align: right;">Page 220</p> <p>1 government payors should be included in your damages 2 calculation? 3 MR. HONIK: Same objection as 4 previously stated. 5 THE WITNESS: It's by instruction of 6 counsel. 7 BY MR. GOLDBERG: 8 Q Whatever counsel told you to 9 calculate, that's what you calculated? 10 MR. HONIK: Objection to form. 11 THE WITNESS: That is not what I said, 12 sir. 13 BY MR. GOLDBERG: 14 Q Whatever counsel told you to include 15 is what you included, and what they told you to 16 exclude is what you tried to exclude. 17 MR. HONIK: Object to form. That is 18 not her testimony. 19 THE WITNESS: That is not my 20 testimony, sir. 21 BY MR. GOLDBERG: 22 Q Going down into this paragraph, you 23 say, "I did not exclude Medicare Part D plan 24 sponsors because they are private entities that 25 offer prescription drug benefits, and I did not</p>
<p style="text-align: right;">Page 219</p> <p>1 THE COURT REPORTER: That was a what? 2 THE WITNESS: A part of the 3 instruction of counsel. 4 BY MR. GOLDBERG: 5 Q Do you understand that you're -- 6 you're excluding them to avoid including claims in 7 your calculation by payors who are excluded from the 8 GPP class definition, such as -- 9 THE COURT REPORTER: Such as -- sorry. 10 Hold on. I didn't hear the end of the 11 question. 12 MR. HONIK: She needs you to repeat 13 it, Seth, the last part, the last part. Jamie, 14 read what you have. 15 MR. GOLDBERG: Such as government 16 payors. 17 MR. HONIK: Object to form and object 18 to the extent it calls for a legal conclusion 19 or expertise. 20 You can answer. 21 THE WITNESS: Thank you. 22 Again, the exclusion was based on 23 instruction from counsel. 24 BY MR. GOLDBERG: 25 Q Do you have any view as to whether</p>	<p style="text-align: right;">Page 221</p> <p>1 exclude federal employee plans because they are 2 provided by private insurers." 3 A There's other things in that sentence 4 as well that you kind of skipped over. 5 Q Again, just focusing on the first part 6 of the sentence, Medicare -- the Medicare Part D 7 plan, part of that -- 8 A Do you mean the second part of the 9 sentence? Do you mean the second? 10 Q No. 11 A I mean, I'm just trying to follow, 12 sir. 13 So the first part of the sentence, 14 which you kind of skipped over half of it, I said, 15 "I also excluded prescriptions for which the 16 consumer is not covered by insurance but uses a 17 coupon that reduces their total costs, including 18 discount cards and vouchers. I did not exclude 19 Medicare Part D plan sponsors because they are 20 private entities that offer prescription drug 21 benefits, and I did not exclude federal employee 22 plans because they are provided by private 23 insurers." 24 Q I want to focus on the Medicare Part D 25 plan part of that. Okay?</p>

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<p style="text-align: right;">Page 222</p> <p>1 In that part of this paragraph, you're</p> <p>2 referring to third-party payors who are private</p> <p>3 insurers that have, as part of their product mix, a</p> <p>4 Medicare Part D plan; am I correct?</p> <p>5 A I don't quite understand your</p> <p>6 question. I'm sorry.</p> <p>7 Q Your sentence says, "I did not exclude</p> <p>8 Medicare part D plan sponsors because they are</p> <p>9 private entities that offer prescription drug</p> <p>10 benefits."</p> <p>11 My question is, you're referring to</p> <p>12 third-party payors who have Medicare Part D plans,</p> <p>13 private entities that have Medicare Part D plans as</p> <p>14 part of their -- their offerings to consumers,</p> <p>15 correct?</p> <p>16 A No.</p> <p>17 MR. HONIK: Object to form.</p> <p>18 BY MR. GOLDBERG:</p> <p>19 Q What are you referring to then?</p> <p>20 A So there are third-party payors, so,</p> <p>21 for example, Aetna. Aetna includes sales plans that</p> <p>22 are to consumers that are -- for people who are</p> <p>23 employed, for people who are in the individual</p> <p>24 insurance market, and also sells plans to consumers</p> <p>25 who may be Medicare eligible.</p>	<p style="text-align: right;">Page 224</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q Do you know whether those Part D plan</p> <p>3 sponsors that are commercial entities receive</p> <p>4 funding from the federal government?</p> <p>5 MR. HONIK: Object to form.</p> <p>6 THE WITNESS: They do under certain</p> <p>7 circumstances, but that's separate from the</p> <p>8 premiums that are paid by actual seniors for</p> <p>9 their insurance coverage.</p> <p>10 BY MR. GOLDBERG:</p> <p>11 Q Did you factor into your calculation</p> <p>12 any amounts that the federal government might have</p> <p>13 paid to private commercial third-party payors that</p> <p>14 offer Medicare Part D plans?</p> <p>15 MR. HONIK: Object to form, asked and</p> <p>16 answered.</p> <p>17 THE WITNESS: Again, consumers who are</p> <p>18 seniors are required to have -- to purchase</p> <p>19 prescription drug benefit from these Part D</p> <p>20 plans. They pay premiums. And then they have</p> <p>21 an insurance schedule on how much they are</p> <p>22 required to pay out-of-pocket for each and</p> <p>23 every prescription drug that is dispensed to</p> <p>24 them.</p> <p>25 Since injury occurs at the point of</p>
<p style="text-align: right;">Page 223</p> <p>1 A Medicare Part D plan is one that is</p> <p>2 sold by commercial insurers such as Aetna, United,</p> <p>3 et cetera, to seniors who are required to have</p> <p>4 Part D prescription drug benefits.</p> <p>5 Q Are you familiar with how</p> <p>6 Medicare Part D claims are reimbursed?</p> <p>7 A I am. But how is that relevant to</p> <p>8 this case, sir?</p> <p>9 Q Do you believe that the TPPs that</p> <p>10 provide Medicare Part D plans bear 100 percent of</p> <p>11 the cost of reimbursement for enrollees of those</p> <p>12 plans?</p> <p>13 MR. HONIK: Object to the form.</p> <p>14 THE WITNESS: I think -- okay. So</p> <p>15 what insurance -- what defines a commercial</p> <p>16 insurance plan is that consumers, you and me,</p> <p>17 my mother, who is Medicare eligible, pay</p> <p>18 premiums to a commercial insurer, as opposed to</p> <p>19 paying premiums or are otherwise insured by a</p> <p>20 private -- by a public insurer.</p> <p>21 Part D plans receive premiums from the</p> <p>22 people who are insured by them, just like the</p> <p>23 plans that are sold to non-seniors receive</p> <p>24 premiums from the people who are insured by</p> <p>25 them. They're exactly the same.</p>	<p style="text-align: right;">Page 225</p> <p>1 sale, it is the insurance price that is paid,</p> <p>2 both by the payor itself, and by the consumer</p> <p>3 at the pharmacy counter, than it is at issue in</p> <p>4 my damage calculation.</p> <p>5 Whether or not there are side payments</p> <p>6 or subsidies or anything else that those plans</p> <p>7 or those consumers may face, is of no moment to</p> <p>8 my economic analysis.</p> <p>9 And the way I like to think about it</p> <p>10 is that if I am injured in a car accident, if I</p> <p>11 receive side payments from my mother, for</p> <p>12 example, to pay for my car repair or pay for</p> <p>13 myself to the -- receive medical treatment,</p> <p>14 that has nothing to do with the economic loss I</p> <p>15 suffered from having -- from being injured,</p> <p>16 from being in a car accident. And therefore,</p> <p>17 those side payments, even if they exist, are of</p> <p>18 no moment in my analysis. Injury occurs at the</p> <p>19 point of sale.</p> <p>20 COURT REPORTER: I'm sorry?</p> <p>21 THE WITNESS: Injury occurs at the</p> <p>22 point of sale.</p> <p>23 BY MR. GOLDBERG:</p> <p>24 Q So did you not factor in that</p> <p>25 third-party payors who offer Medicare Part D plans</p>

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<p style="text-align: right;">Page 226</p> <p>1 receive respective subsidies from the federal 2 government to cover their beneficiaries' 3 prescription drug purchases? 4 MR. HONIK: Object to form, asked and 5 answered. 6 THE WITNESS: Again, they only do so 7 sometimes in a prospective way. Largely, those 8 payments are made retrospectively and only for 9 certain types of prescription drugs. I have 10 not seen any evidence to suggest that the 11 valsartan products at issue in this case were 12 ones that were either directly paid by the 13 federal government or were part of those 14 retrospective payments that the government 15 might have made. 16 Usually, those type of direct 17 payments, or retrospective payments, are made 18 for really expensive specialty drugs used in 19 the cancer setting, in the immunology setting, 20 with prices of \$10,000 or more for treatment. 21 That's not what we're talking about in this 22 case. 23 BY MR. GOLDBERG: 24 Q But you haven't considered any amount 25 that the federal government might have paid to any</p>	<p style="text-align: right;">Page 228</p> <p>1 donut hole, they would have to spend something 2 like \$400, maybe a little bit more, in order to 3 even get into that phase of the benefit. 4 And I think the limit for catastrophic 5 coverage during this time period is more like 6 \$8,000. 7 COURT REPORTER: Is what? 8 THE WITNESS: Is more like \$8,000. 9 BY MR. GOLDBERG: 10 Q Yes or no -- 11 A It's not a yes or no question, sir. 12 Q This -- let me ask the question. 13 Yes or no, did you factor in any 14 payments made by the federal government to 15 third-party payors offering Medicare Part D plans? 16 Yes or no, did you factor that into your 17 calculation? 18 MR. HONIK: Object to form, asked and 19 answered. You can't direct the witness to 20 answer it in a manner in which you'd like. If 21 she tells you she's unable to answer it yes or 22 no, she can provide an answer. 23 Please do so. 24 THE WITNESS: Thank you. 25 So, again, the vast majority of</p>
<p style="text-align: right;">Page 227</p> <p>1 TPPs for -- in connection with their Medicare Part D 2 plans, right? 3 MR. HONIK: Object to the form, asked 4 and answered. 5 THE WITNESS: Again, I'm not aware of 6 any evidence to suggest that third-party payors 7 receive direct payments from the federal 8 government to underwrite any senior's sale or 9 purchase of valsartan at-issue products in this 10 case. 11 Again, usually those type of payments 12 in the catastrophic limit, for example, of 13 Part D, those are payments that are made either 14 retrospectively after the injury would have 15 occurred, or are for products that are not at 16 issue here. They're for drugs that are really 17 expensive and for which patients have blown 18 through the donut hole, are in the catastrophic 19 phase of their benefit design. That's -- 20 that's not what we're talking about here. 21 These are generic products that are -- 22 I think, you know, the average co-insurance 23 amount that I -- that I calculated was 24 somewhere on the order of \$12. Consumers 25 could, I think -- to get out of the -- into the</p>	<p style="text-align: right;">Page 229</p> <p>1 seniors who have prescription drug benefits 2 through Part D -- my mother is one of them. I 3 might know more about this than I should. They 4 pay premiums, and they also pay at the pharmacy 5 counter when they get a prescription at a 6 low-cost generic, such as the at-issue 7 valsartan in this case. 8 So that -- whether -- if those TPPs, 9 those third-party payors receive side payments 10 from the federal government, or other types of 11 payments from the federal government, is really 12 not material to this because there's no 13 evidence to suggest that low-cost generics are 14 ever in that phase of the benefit where the 15 third-party payor would actually pay the side 16 payments. 17 BY MR. GOLDBERG: 18 Q What do you understand the third-party 19 payors' point of sale to be? You mentioned the 20 consumer paying at the retail pharmacy. What do you 21 understand the TPPs' point of sale to be? 22 A When the consumer goes to fill their 23 prescription at the pharmacy counter, the pharmacy 24 runs a check on what insurance that patient has and 25 how much the patient needs to pay out of pocket.</p>

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<p style="text-align: right;">Page 230</p> <p>1 The point of sale for both, what the pharmacy 2 expects to receive from the consumer and what the 3 pharmacy expects to receive from the insurer is 4 exactly the same. 5 Those transactions occur within 6 seconds, and the pharmacy dispenses the product to a 7 consumer predicated on their existence of insurance 8 and the insurance saying that, yes, they will pay 9 for that product, dispense that beneficiary. It's 10 exactly the same. 11 Q We were -- you talked a lot about 12 value and therapeutic value of the at-issue 13 valsartan, what the consumers receive. And you 14 explained that there was an illegitimate supply for 15 at-issue valsartan, and therefore, even though there 16 was a demand, the drug was worthless. Is that the 17 same -- that worthless as to consumers, is that the 18 same as to third-party payors? 19 MR. HONIK: Object to the form. It's 20 a little bit -- 21 THE COURT REPORTER: I'm sorry. I 22 didn't hear the end of the question. 23 MR. HONIK: Sorry. You trailed off, 24 Seth. Just cover the -- 25</p>	<p style="text-align: right;">Page 232</p> <p>1 legitimate supply curve based on the assumptions 2 given to me by counsel. 3 Q And regardless of any benefit that a 4 TPP might have received, they got from their 5 insured's treatment with the at-issue valsartan, 6 your view is that the drug, as to that TPP, is still 7 worthless? 8 MR. HONIK: Object to form, asked and 9 answered. 10 THE WITNESS: I'm sorry. I didn't -- 11 really did not follow your question. There's a 12 lot of compound phrases there. Can you please 13 restate? 14 BY MR. GOLDBERG: 15 Q Regardless of any benefit that a TPP 16 might have perceived they received from their 17 insured's treatment with the at-issue valsartan, as 18 to that TPP, the drug is still worthless in your 19 view? 20 MR. HONIK: Object to the form, asked 21 and answered. 22 THE WITNESS: I don't understand what 23 you mean by a third-party payor receiving value 24 or benefit. Can you please define? 25</p>
<p style="text-align: right;">Page 231</p> <p>1 BY MR. GOLDBERG: 2 Q Is your view that there was an 3 illegitimate supply of valsartan as to consumers the 4 same for TPPs? 5 MR. HONIK: Object to form. 6 THE WITNESS: I don't think that's the 7 question you asked me, sir. 8 BY MR. GOLDBERG: 9 Q Well, I'm asking you that question. 10 A Okay. Can you go back and ask that 11 question again because I was focused on trying to 12 get clarity on the previous question that you asked. 13 Q Is your view that there was an 14 illegitimate supply of at-issue valsartan as to 15 consumers the same for TPPs? 16 A I was asked to assume that there is no 17 legitimate supply of adulterated and misbranded 18 prescription drugs for the at-issue valsartan 19 products between 2012 and 2018 in order to calculate 20 damages in this matter. For both consumers and 21 end-party payors that are -- that are included in 22 the class. 23 As we have already discussed, my 24 assessment assumes there's a demand curve. What my 25 assessment does not do is assume that there is a</p>	<p style="text-align: right;">Page 233</p> <p>1 BY MR. GOLDBERG: 2 Q Does a third-party payor receive a 3 value when its insureds are effectively treated with 4 a drug? 5 MR. HONIK: Object to the form. 6 They're not consuming -- they're not consuming 7 drugs. I think -- I think that's the problem, 8 Seth. 9 THE WITNESS: I don't follow. 10 MR. HONIK: You're kind of mixing 11 apples and oranges, I think. 12 THE WITNESS: There is no therapeutic 13 value to the third-party payor. 14 BY MR. GOLDBERG: 15 Q Does a third-party payor -- 16 A I don't even understand that, that 17 context. 18 Q Does a third-party payor receive an 19 economic value when its insureds are effectively 20 treated with at-issue valsartan? 21 MR. HONIK: Object to the form of the 22 question. 23 THE WITNESS: That's a lot -- again, 24 that's a lot of compound statements and 25 assumptions that you're making.</p>

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<p style="text-align: right;">Page 234</p> <p>1 BY MR. GOLDBERG:</p> <p>2 Q Well, let's just --</p> <p>3 A Again, third-party payors are not</p> <p>4 consumers, so they don't receive any therapeutic</p> <p>5 benefit from their beneficiaries consuming a</p> <p>6 product. And they certainly don't receive any --</p> <p>7 any benefit from consumers consuming a product that</p> <p>8 was adulterated and misbranded and may have actually</p> <p>9 caused clinical harm.</p> <p>10 Q Do you have any evidence that there</p> <p>11 was any clinical harm in this case from 2012 to</p> <p>12 2018?</p> <p>13 MR. HONIK: Object to the form,</p> <p>14 outside the scope.</p> <p>15 THE WITNESS: I don't think that's the</p> <p>16 issue. Again, that's why -- that's why I don't</p> <p>17 understand at all. I mean --</p> <p>18 BY MR. GOLDBERG:</p> <p>19 Q Just --</p> <p>20 A Okay. I'm sorry, Mr. Goldberg.</p> <p>21 You've interrupted me over and over again today.</p> <p>22 There is a word for that, it's mansplaining. Please</p> <p>23 let me finish.</p> <p>24 So, again, I don't understand the idea</p> <p>25 that third-party payors could benefit from consumers</p>	<p style="text-align: right;">Page 236</p> <p>1 And in Paragraph 52, you describe</p> <p>2 third-party payors.</p> <p>3 A Is that a question?</p> <p>4 Q Are you aware -- are you familiar with</p> <p>5 the different contractual arrangements that</p> <p>6 third-party payors have in terms of sourcing and</p> <p>7 paying for and being reimbursed for at-issue</p> <p>8 valsartan?</p> <p>9 A I think I'm -- that was a compound</p> <p>10 question, right?</p> <p>11 So what do you mean by third-party</p> <p>12 payors being paid for?</p> <p>13 Q Okay. Are you -- are you familiar</p> <p>14 with the contractual arrangements that third-party</p> <p>15 payors have, say, with pharmacy benefit managers?</p> <p>16 A Pharmacy benefit managers are a member</p> <p>17 of the supply chain of prescription drugs in the</p> <p>18 United States. And some payors have their own PBM,</p> <p>19 so there is no contractual relationship. They all</p> <p>20 have a PBM, and some third-party payors contract</p> <p>21 with PBMs to provide fund services to their</p> <p>22 beneficiaries.</p> <p>23 Q These are differences from third-party</p> <p>24 payor to third-party payor, right?</p> <p>25 A I really don't understand that</p>
<p style="text-align: right;">Page 235</p> <p>1 taking adulterated prescription drugs. That should</p> <p>2 not -- that, I was asked to assume, should not have</p> <p>3 entered into the U.S. class of trade. That</p> <p>4 is -- that is your assumption of your -- underlying</p> <p>5 your hypothetical question.</p> <p>6 THE COURT REPORTER: Seth, when you</p> <p>7 get to a good point, can we take five minutes,</p> <p>8 please?</p> <p>9 MR. GOLDBERG: Yes, this is a good</p> <p>10 time.</p> <p>11 MR. HONIK: Okay. Let's take five,</p> <p>12 and then we will reassess --</p> <p>13 THE VIDEOGRAPHER: The time is 5:37.</p> <p>14 This ends Media Unit Number 5. We're going off</p> <p>15 the record.</p> <p>16 (Whereupon, a short break was taken.)</p> <p>17 THE VIDEOGRAPHER: The time is 5:50.</p> <p>18 This begins Media Unit Number 6. We're back on</p> <p>19 the record.</p> <p>20 BY MR. GOLDBERG:</p> <p>21 Q So in your report, you talk about the</p> <p>22 different levels of the pharmaceutical supply chain?</p> <p>23 A Where are you referring, Mr. Goldberg?</p> <p>24 Q I'm going to get you there. It starts</p> <p>25 at Page 19 and goes through to Page 22.</p>	<p style="text-align: right;">Page 237</p> <p>1 question. I'm sorry.</p> <p>2 Q Each third-party payor has its own set</p> <p>3 of contractual arrangements that control its</p> <p>4 distribution and -- and insurance of at-issue</p> <p>5 valsartan?</p> <p>6 MR. HONIK: Object to form.</p> <p>7 THE WITNESS: That is not my</p> <p>8 testimony. Like I just said, the biggest</p> <p>9 payors in the U.S. are their own PBM. They own</p> <p>10 their own PBM, so there is no contractual</p> <p>11 relationship. They are the PBM. There are</p> <p>12 some payors that contract for external PBM</p> <p>13 services, and there's some third-party payors</p> <p>14 that directly go with pharmacies to dispense</p> <p>15 drugs to their beneficiaries.</p> <p>16 BY MR. GOLDBERG:</p> <p>17 Q Are there other -- are there other</p> <p>18 arrangements that you can think of that third-party</p> <p>19 payors have?</p> <p>20 A Not -- I mean, that -- those are</p> <p>21 general buckets that characterize third-party</p> <p>22 payment for prescription drugs sold in the pharmacy</p> <p>23 setting.</p> <p>24 Q Do third-party payors pay pharmacies</p> <p>25 directly, to your understanding?</p>

60 (Pages 234 - 237)

RESTRICTED CONFIDENTIAL

<p style="text-align: right;">Page 238</p> <p>1 A They can and do or dispense</p> <p>2 prescription drugs every day.</p> <p>3 Q Are you aware of any contractual</p> <p>4 arrangements a third-party payor was not able to</p> <p>5 keep and satisfy as a result of the sale of at-issue</p> <p>6 valsartan?</p> <p>7 MR. HONIK: Object to form, outside</p> <p>8 the scope.</p> <p>9 THE WITNESS: I don't understand your</p> <p>10 question at all. I'm sorry, what does "keep"</p> <p>11 mean here?</p> <p>12 BY MR. GOLDBERG:</p> <p>13 Q Are you aware of any -- any</p> <p>14 arrangement a third-party payor has that it's not</p> <p>15 able to satisfy as a result of at-issue valsartan?</p> <p>16 MR. HONIK: Same objection.</p> <p>17 THE WITNESS: I don't know what you're</p> <p>18 referring to. I'm sorry. I don't follow.</p> <p>19 BY MR. GOLDBERG:</p> <p>20 Q Are you aware of whether any</p> <p>21 third-party payor did not -- ended up reaching a</p> <p>22 contract with a pharmacy benefits manager because of</p> <p>23 their covering at-issue valsartan?</p> <p>24 MR. HONIK: Same objection.</p> <p>25 And to the extent it calls for a legal</p>	<p style="text-align: right;">Page 240</p> <p>1 known contaminants of nitrosamines in these</p> <p>2 products.</p> <p>3 BY MR. GOLDBERG:</p> <p>4 Q Does it matter to your analysis that</p> <p>5 the specifications for valsartan during that time</p> <p>6 period did not require -- or did not include</p> <p>7 nitrosamines?</p> <p>8 MR. HONIK: Object to the form,</p> <p>9 hypothetical, inappropriate, facts not in</p> <p>10 evidence.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: Again, the manufacturers</p> <p>13 themselves attested on their drug forms to the</p> <p>14 Food and Drug Administration that there was no</p> <p>15 contamination.</p> <p>16 BY MR. GOLDBERG:</p> <p>17 Q My question is, does it matter to your</p> <p>18 analysis that there -- that nitrosamines were not</p> <p>19 included in the specifications for valsartan from</p> <p>20 2012 to July 2018?</p> <p>21 MR. HONIK: Object to the form,</p> <p>22 improper hypothetical. Those are not</p> <p>23 dispensed.</p> <p>24 You may answer.</p> <p>25 THE WITNESS: Again, my understanding</p>
<p style="text-align: right;">Page 239</p> <p>1 conclusion, you may answer if you understand.</p> <p>2 THE WITNESS: I don't understand the</p> <p>3 question. I'm sorry. Like I said before,</p> <p>4 there are a variety of different types of</p> <p>5 arrangements. Many third-party payors -- many</p> <p>6 insurers pay pharmacies directly for dispensed</p> <p>7 drugs. Some third-party payors may contract</p> <p>8 with pharmacy benefit managers for the coverage</p> <p>9 of some drugs.</p> <p>10 I think what you're referring to is</p> <p>11 the latter category, but I really -- I don't</p> <p>12 understand your question. I don't know what</p> <p>13 you mean by "keep a contract" in this setting.</p> <p>14 BY MR. GOLDBERG:</p> <p>15 Q Does it matter to your analysis that</p> <p>16 different -- there were different levels of NDMA or</p> <p>17 NDEA in the manufacturer defendants' valsartan?</p> <p>18 MR. HONIK: Object to the form. Facts</p> <p>19 not in evidence.</p> <p>20 You may answer.</p> <p>21 THE WITNESS: Thank you.</p> <p>22 So my understanding is, during the</p> <p>23 at-issue time period, between January 2012 and</p> <p>24 2018, the manufacturers attested to the</p> <p>25 Food and Drug Administration that there were no</p>	<p style="text-align: right;">Page 241</p> <p>1 is that the manufacturers of the at-issue</p> <p>2 valsartan products attested to the</p> <p>3 Food and Drug Administration over and over</p> <p>4 again that these products were manufactured to</p> <p>5 be compliant, at minimum, with cGMP. And they</p> <p>6 also attested to the fact that there were no</p> <p>7 contamination of nitrosamines in these at-issue</p> <p>8 valsartan.</p> <p>9 MR. GOLDBERG: I see we're at</p> <p>10 6 o'clock?</p> <p>11 MR. HONIK: Yeah. Why don't we go off</p> <p>12 the record, video and steno?</p> <p>13 THE VIDEOGRAPHER: The time is</p> <p>14 6 o'clock. We're going off the record.</p> <p>15 (Whereupon, the deposition concluded</p> <p>16 at 6 o'clock p.m.)</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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Page 242	Page 244
<p>1 CERTIFICATE</p> <p>2</p> <p>3 I, Jamie I. Moskowitz, a Shorthand</p> <p>4 (Stenotype) Reporter and Notary Public, do hereby</p> <p>5 certify that the foregoing Deposition, of the</p> <p>6 witness, RENA M. CONTI, Ph.D., taken at the time and</p> <p>7 place aforesaid, is a true and correct transcription</p> <p>8 of my shorthand notes.</p> <p>9 I further certify that I am neither</p> <p>10 counsel for nor related to any party to said action,</p> <p>11 nor in any way interested in the result or outcome</p> <p>12 thereof.</p> <p>13 IN WITNESS WHEREOF, I have hereunto set</p> <p>14 my hand this 16th day of February, 2022.</p> <p>15</p> <p>16 <i>Jamie Ilyse Moskowitz</i></p> <p>17 Jamie Ilyse Moskowitz</p> <p>18 License No. XI01658</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 In Re: Valsartan, Losartan, Et Al</p> <p>2 Rena Conti, PH.D (#5064909)</p> <p>3 E R R A T A S H E E T</p> <p>4 PAGE _____ LINE _____ CHANGE _____</p> <p>5 _____</p> <p>6 REASON _____</p> <p>7 PAGE _____ LINE _____ CHANGE _____</p> <p>8 _____</p> <p>9 REASON _____</p> <p>10 PAGE _____ LINE _____ CHANGE _____</p> <p>11 _____</p> <p>12 REASON _____</p> <p>13 PAGE _____ LINE _____ CHANGE _____</p> <p>14 _____</p> <p>15 REASON _____</p> <p>16 PAGE _____ LINE _____ CHANGE _____</p> <p>17 _____</p> <p>18 REASON _____</p> <p>19 PAGE _____ LINE _____ CHANGE _____</p> <p>20 _____</p> <p>21 REASON _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 Rena Conti, PH.D Date _____</p> <p>25</p>
Page 243	Page 245
<p>1 Ruben Honik, Esq.</p> <p>2 ruben@honiklaw.com</p> <p>3 February 16, 2022.</p> <p>4 RE: In Re: Valsartan, Losartan, et al.</p> <p>5 2/10/22, Rena Conti, PH.D. (#5064909)</p> <p>6 The above-referenced transcript is available for</p> <p>7 review.</p> <p>8 Within the applicable timeframe, the witness should</p> <p>9 read the testimony to verify its accuracy. If there are</p> <p>10 any changes, the witness should note those with the</p> <p>11 reason, on the attached Errata Sheet.</p> <p>12 The witness should sign the Acknowledgment of</p> <p>13 Deponent and Errata and return to the deposing attorney.</p> <p>14 Copies should be sent to all counsel, and to Veritext at</p> <p>15 cs-ny@veritext.com</p> <p>16</p> <p>17 Return completed errata within 30 days from</p> <p>18 receipt of testimony.</p> <p>19 If the witness fails to do so within the time</p> <p>20 allotted, the transcript may be used as if signed.</p> <p>21</p> <p>22 Yours,</p> <p>23 Veritext Legal Solutions</p> <p>24</p> <p>25</p>	<p>1 In Re: Valsartan, Losartan, et al.</p> <p>2 Rena Conti, PH.D (#5064909)</p> <p>3 ACKNOWLEDGEMENT OF DEPONENT</p> <p>4 I, Rena Conti, PH.D, do hereby declare that I</p> <p>5 have read the foregoing transcript, I have made any</p> <p>6 corrections, additions, or changes I deemed necessary as</p> <p>7 noted above to be appended hereto, and that the same is</p> <p>8 a true, correct and complete transcript of the testimony</p> <p>9 given by me.</p> <p>10 _____</p> <p>11 _____</p> <p>12 Rena Conti, PH.D Date _____</p> <p>13 *If notary is required</p> <p>14 SUBSCRIBED AND SWORN TO BEFORE ME THIS</p> <p>15 _____ DAY OF _____, 20____.</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 NOTARY PUBLIC</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

RESTRICTED CONFIDENTIAL

[& - 23]

Page 1

&	11:30 57:16	2	177:4,4,11,12
& 2:16,20 3:17	11:57 74:6	2 8:4 12:24 52:25	199:12,17 231:19
4:18 5:2,7,11 6:2	12 10:4 70:4	53:3,5,15 54:3	234:12 239:24
6:12,17 7:2 14:13	227:24	74:10 77:6,14	240:20
0	12-29-21 69:6	78:21 80:23,23	2019 76:7 171:2
0 57:24 216:18	12.75 68:24 72:23	112:22 166:18,21	202.452.7900 4:21
02109 6:14	12:11 74:9	181:18,22	202.624.2500 5:15
07068 2:9	12:16 76:23	2.6 66:22	202.776.7800 3:14
07102 6:10	12:18 77:2	2/10/22 243:5	2020 35:10,15 39:9
08540 5:21	12:42 91:22 92:1	20 15:3,17 17:2	40:7,14 41:10
1	12:46 94:17	28:5 73:12 98:20	42:7,9 59:24 60:1
1	12:48 95:11	245:15	61:1 78:7
1 8:3 11:3 43:16	13 70:5	20004 3:13 5:14	2021 26:4,11,15,17
43:17 44:2 49:15	13th 168:6	20006 4:20	45:23 48:3 62:19
58:6,8 74:7 75:1,8	1400 7:4	2000s 40:20	68:20 69:12 71:15
79:8 80:22,23	15 57:3 69:13 70:6	2003 38:20	71:16 72:8,14,15
166:22	200:4	2005 38:20	72:19,22 73:1,2,3
10 1:12 47:23,23	1515 2:4	2007 38:18 41:5,24	73:6
74:4 128:20 150:4	15219 3:20 6:4	2008 41:24	2022 1:12 11:2
10,000 226:20	15th 6:9	2010 39:5,13 40:7	27:2 54:6 71:14
10.75 72:18	16 70:6 243:3	40:13 41:3,9,10	73:2,4,9 242:14
100 2:13 6:9 49:6	167 8:11	42:9 43:1	243:3
49:7,21 202:16	16th 242:14	2011 39:5 43:1	20th 184:16
204:20 223:10	17 53:23 56:4	2012 43:1 78:7,11	21 5:20
100,000 26:14	218:19	127:7,17 130:2,13	21024 67:17
1000 3:13	1700 4:20	130:24 131:21	21158 63:9,20
1001 5:14	17th 3:6	132:7,20,23 139:1	68:11
10013 2:18	18 174:15 176:10	139:13 149:18	212.355.9500 2:18
10019-6119 6:19	18th 167:24	150:21 165:5	212.415.9357 6:19
101 125:13,15	168:11 173:22	199:11,16 231:19	214.855.8221 4:12
126:19 188:20,23	19 235:25	234:11 239:23	215.979.1000 3:7
189:2,15	190 4:15	240:20	21617 68:23 72:6
103 2:8	19038 12:25	2018 76:7 78:7,11	72:11
10:07 74:4	1906 204:19	127:7,17 130:2,14	22 103:6 235:25
10:17 1:13 11:2	19102 2:4	130:25 131:21	2200 4:11
10th 11:2 47:3	19103 3:7	132:8,20,23 139:1	2220 6:24
11 5:8	1:12 112:9	139:13 149:18	227 5:4
1100 2:4	1:13 112:21	150:21 165:5	23 95:14,17,17,18
1154 242:16	1:45 112:19	167:24 168:6,11	96:13 97:1,16,18
11:29 57:13	1:53 112:25	171:1 173:22	98:20 99:1 101:25
		174:15 176:10	104:16

RESTRICTED CONFIDENTIAL

[230 - activities]

Page 2

230 6:24	80:23 81:19 88:8	60 72:25	9th 3:13
242 10:7	180:14	600 4:15 5:4	a
243 10:8	400 228:2	6001 2:13	a.m. 1:13
24th 68:20	412.263.4397 6:5	60601 4:5	able 71:21 73:17
25 49:2	412.560.3300 3:20	60606 6:24	87:9 210:12 238:4
250 2:17	42 152:1	609.924.0808 5:21	238:15
26 184:12	43 8:3	60s 187:10	abraham 5:18
267.435.1300 2:5	45 201:10,15,17	617.213.7045 6:15	abstracts 54:4
27th 6:14	45202-4029 7:4	63105 4:16	academic 17:20
28 177:12	46204 5:9	64 58:19	academy 15:25
28202 5:4	464 218:15	65 56:11	accept 163:7,9
2875 1:2	4:02 180:13	66 43:10,23 44:1	177:9
29 217:10	4:41 206:8	67 58:14,20,21	access 36:15,18,23
29th 69:12	4:52 206:11	675 49:15 60:11	accident 196:22
2:44 150:13	5	7	196:23 225:10,16
2:55 150:16	5 8:10 74:16,17	7 114:21 128:19	account 193:1,11
3	167:9 206:12	7-18-2018 168:15	202:25 203:11
3 8:6 53:15,15	235:14	7-24-2018 173:15	211:21,23
56:16,20 57:20	50 49:4 204:19	70 58:14,14	accounted 212:11
76:14 77:15,18,22	504.524.5777 2:25	701 2:24	accounting 49:12
80:23 104:25	505 3:13	70130 2:24	73:12
113:1 166:22	5064909 243:5	704.444.3475 5:5	accuracy 243:9
180:10	244:2 245:2	74 8:10	accurate 84:3
30 3:6 243:17	51 6:18	75 217:11,12	182:1
300 4:20	512.795.8686 2:14	750 60:20	achieve 154:4
3100 4:5	513.698.5000 7:5	75201-7932 4:11	acknowledge
312 7:4	52 8:4 52:22,23	757.1100 6:10	11:17,21
312.456.1065 4:6	236:1	77 4:5	acknowledgement
312.566.4803 6:25	52nd 6:18	775 60:20,22	245:3
314.480.1500 4:16	53 6:14	78746 2:13	acknowledging
317.236.1313 5:9	56 8:6	8	170:14
32nd 3:19	58 8:9 206:16	8 10:5 57:9	acknowledgment
36,000ish 218:17	5:37 235:13	8,000 228:6,8	243:12
3600 4:11	5:50 235:17	80 211:17	acquisition 61:10
38th 6:4	6	80,000 26:14	action 12:18 24:24
3:37 180:9	6 8:11 57:1 104:24	9	25:5,5,7 75:7
4	113:4 121:5	92 210:16	242:10
4 8:9 53:15 58:16	128:19 167:1,2,6	973 6:10	actions 1:5
58:22,23 59:3	235:18 241:10,14	973.228.9898 2:9	actively 72:3
76:14 77:15,18,23	241:16		activities 71:20

RESTRICTED CONFIDENTIAL

[activity - andrast]

Page 3

activity 71:3	130:14,18 131:7	140:14,20 141:2	alluded 104:21,22
actual 50:23,23	131:15 132:2	149:16 150:19	alternative 169:19
224:8	133:4 138:9 139:8	151:10 158:18	171:11 192:7
adam 2:7	152:3 165:6 170:1	159:5,19,22,23	193:12 194:7
adap 218:5	171:20 172:10,13	160:15 161:6,20	198:19
adaps 218:5	173:19 179:23	163:6,20 177:14	alternatives 194:3
added 62:20	182:15,16 183:4	190:16	amended 52:23
addition 14:11	183:19 184:14	agreed 204:6	75:7
43:7 71:18,19	185:16,18,20	agreement 8:3	america 191:7
72:22 83:22	186:2 187:1,16	43:13 44:6,7	american 118:11
113:13 115:8,9,25	189:22 194:14,23	49:14	125:3 134:12
190:12 191:23	197:12,13 199:8	agrees 204:24	171:6 174:3
additional 104:22	199:21 200:13	205:2	176:12 177:21
146:9	202:13 231:17	ahead 32:15 131:3	180:4
additions 245:6	234:8 235:1	131:25 152:14,14	americans 137:10
address 12:23	adulteration 41:22	159:13 160:12	162:25
administered	79:5,12 80:11,21	aid 5:10	amerisourceberg...
11:22	81:2,4,23 84:10	al 243:4 244:1	7:5
administration	103:14,19,21,22	245:1	amount 35:25
22:5 48:22 89:10	115:16 166:2	albertsons 4:21	226:24 227:23
96:16 97:14 98:3	176:8	5:5	amounts 72:25
98:16 110:16	adulterations	alek 3:5	209:7,8 211:16
113:22 115:13	201:2	alfano 6:2	212:9,13 224:12
116:3,20 118:10	advent 136:1,2	allotted 243:20	analyses 64:10
118:17,20 121:7	advised 165:11,18	allow 33:19 101:5	analysis 46:17
123:6 185:7	216:25	120:11 125:8,25	50:8 61:11 63:14
239:25 240:14	aetna 222:21,21	186:5 202:18	63:25 64:4 65:4
241:3	223:2	214:22 215:15	123:14,20,21,22
administration's	affairs 218:9	216:3	139:6,19 146:14
98:6 114:8,18	affiliate 17:20	allowance 81:24	164:6,8,12 165:8
121:21 122:3	affirmatively 31:7	allowed 88:23	192:25 193:10
130:15 145:20	aforesaid 242:7	110:8 113:14,19	194:8 196:12
admins 48:18	afraid 181:5	113:23 115:21	198:15,23,25
adulterated 76:7	agencies 20:14	116:17,23 119:7	199:19,20 204:7
78:15,23 79:11,14	22:7 23:2	120:16 126:10	205:15 212:12,15
81:8 103:8,11,15	aggregate 215:6	146:7 148:2,7,9	212:16 225:8,18
103:16,25 104:3,4	ago 111:23 155:10	149:6 156:21	239:15 240:4,18
104:13,18 105:3	155:12	161:14 182:17	analyzing 131:13
111:12 114:24	agree 34:2 46:23	197:15 204:22	andras 4:3
115:17 118:14	98:18,19 119:1	allows 125:12	andrast 4:3
122:12 124:9,19	132:6 137:2	213:23	

RESTRICTED CONFIDENTIAL

[angiotensin - asked]

Page 4

angiotensin 8:12 167:7 announced 165:12 166:10 announcements 8:12 167:7 annual 26:10 annually 107:15 107:18 answer 9:3 13:11 13:11,17 30:17,23 31:9,22 32:1,17 33:15 34:18 45:6 45:10,14 54:16 55:1,25 56:5 64:21,21 80:14 81:6 86:18 92:5 92:15 99:18,25 101:14 106:15 109:8,14,24 112:3 125:21 127:22 128:7,22 132:5,21 142:9,18 143:4 147:13,14 150:25 155:1,17,24 156:10 157:8 158:4 159:9,14,16 160:11,13,14 161:19 162:1,9 163:19 164:18 166:7 174:25 176:4 179:6,10 180:22 181:4 186:11,17 187:20 188:14,25 196:16 196:20 201:5 209:21 215:11 219:20 228:20,21 228:22 239:1,20 240:11,24	answered 31:6 56:6 61:21,23 77:11 82:11,25 83:5 84:25 86:16 88:21 89:21 90:21 94:10,12 97:10,23 98:23 102:8,22 104:10 106:3 107:6,25 108:7,23 110:23 117:12 119:4 121:3 125:20 126:18 129:20 130:4 131:2,24 132:10 138:20 140:10,24 141:25 143:3 144:25 145:18 147:11,22 148:21 151:19 156:9 157:7 158:2,22 160:3 163:22,23 164:17 165:23 169:21 170:18 171:17 174:24 176:3,22 177:19 178:12,24 179:12 179:12,18 182:24 188:22 194:10 196:14,19 198:17 199:6 200:4 205:12 214:13 215:5,19 224:16 226:5 227:4 228:19 232:9,21 answering 100:19 126:13 answers 13:6 120:24 antitrust 17:15 18:4,8,10,25 19:15 19:20 24:18 31:24	anybody's 48:17 appear 50:14 appears 173:23 appended 245:7 appendices 50:25 apples 233:11 applicable 243:8 application 89:11 applied 96:21 97:20 212:14 apply 102:5 207:3 apportion 65:9 appreciate 188:11 appropriate 55:2 109:9 128:10 212:17,19 approval 157:16 approve 119:21 approved 124:14 approves 118:17 118:21 approximately 26:14 69:13 70:6 72:25 210:16 211:17 arb 8:13 192:13,13 198:12 area 40:15 206:2 arising 197:23 arrangement 12:1 238:14 arrangements 236:5,14 237:3,18 238:4 239:5 arrive 182:19 arrived 34:12 183:1 article 40:14,14 articles 23:13 39:25 54:3	aside 45:20 84:19 132:6 207:20 208:12 asked 13:16 27:22 32:4 47:11 51:22 57:3 61:20 70:15 70:16 76:3 77:10 78:14,20,22,25 79:5,10 81:3,11,16 82:10,24 83:4 84:24 88:20 89:20 90:20 94:9 96:4 96:12,19,25 97:6,9 97:11,22 98:4,13 98:22 100:20 101:21 102:7,10 102:16,18,21 103:14,21 104:2,9 104:17 106:2 107:5,24 108:6,22 109:19 110:22 117:11 119:3 121:2 125:19 126:17 127:23 128:18 129:19 130:3,12 131:1,23 132:1,9 133:3 138:8,19 139:7 140:9,23 141:24 143:2,18 144:25 145:17 146:24 147:10,12,21 148:8,20 149:8 151:18 156:8 157:7 158:2,21 160:2,4 161:3 163:21 164:16 165:3,22 169:13 169:20,24 170:17 171:16 174:23 176:3,21 177:19
--	---	---	---

RESTRICTED CONFIDENTIAL

[asked - back]

Page 5

178:11,23 179:11 179:17 182:14,23 183:3 188:21 194:9,21 196:13 196:18 197:6,9,11 198:16 199:5 200:4 203:25 206:19 214:12 215:3,5,18 224:15 226:4 227:3 228:18 231:7,12 231:16 232:8,20 235:2 asking 12:19 19:11,12 32:8 42:6 54:19,20 87:17,18 99:8 116:11 127:9,12 128:21 129:14 132:12 143:11 161:18 166:16 187:18 189:21 190:25 191:4 203:19 215:7 231:9 aslater 2:8 aspect 22:9 79:9 aspects 86:5 assert 13:10 assessed 91:13 assessing 133:6 210:7 assessment 89:2 169:17 198:6 231:24,25 assessments 156:14 assign 111:11 assigned 111:10 assigning 201:17 204:16	assignment 139:20 147:24 assistance 217:22 218:4,6 assists 50:5 associate 14:8 16:14 associated 145:21 145:22 147:25 149:10 192:6 194:22 204:1 208:18 associates 16:23 27:21 44:14 59:6 assume 13:17 76:3 78:15,22 79:5,11 80:24 81:3 96:4 96:12,19,25 97:6 97:11 98:4,13 101:21 102:10,16 102:18 103:14,21 104:2,17 130:12 131:14 132:2 133:4 138:8 139:7 148:8 149:8 161:3 165:3 169:24 177:8 178:18 182:14 183:3 197:11 231:16,25 235:2 assumed 80:12,19 assumes 231:24 assuming 62:13 63:8 64:5,20,24 assumption 79:1 80:20 81:12,16 177:9 235:4 assumptions 132:6 143:18 197:2 232:1 233:25	assurance 88:17 88:19 89:1,14,17 89:18 90:5,19 attached 94:8 243:11 attaches 180:21 attachment 83:13 83:15,16 84:16,23 85:8,10 91:11 92:20 attack 135:8,12,21 136:6 137:17 attacks 134:8,19 134:21 135:25 136:10 137:12 attempt 205:8 attest 88:25 106:17 107:11 110:13 115:23 attestation 89:4 107:15 108:16 116:6,12 117:1,10 117:14 118:3 attested 116:1 163:15 190:11 239:24 240:13 241:2,6 attesting 119:23 123:9 131:10 attorney 68:18 243:13 attorneys 11:16 27:23 44:8 46:5 46:11 70:14 attributable 136:6 audit 210:20 augusteijn 61:2 aurobindo 3:21 78:2 93:25 austin 2:13	authored 39:24 54:6,6 authority 125:15 availability 46:6 141:17 available 132:14 132:15,18 134:22 145:24 148:24 171:20 172:3 174:7 191:13 192:22 243:6 avenue 4:11 5:14 average 212:12 216:17 227:22 averaging 216:19 avoid 219:6 avoiding 137:2,17 awarded 41:5,5 aware 41:21 42:1 43:6,8 119:15 134:7 135:13 138:25 139:12 147:16,19 155:2 155:11,19 165:18 166:8 167:15 170:24 171:3 210:9 227:5 236:4 238:3,13,20 awesome 178:15 awsmolij 3:5 b b 3:6 5:3 6:22 8:1 83:13 84:23 85:10 91:11 92:20 217:23 218:1 back 23:4,6 24:3 35:7 51:6 52:7,9 57:17 59:24 64:25 66:16 73:13 74:4 74:10 77:3 88:7 92:2 95:1,12
---	---	--	---

RESTRICTED CONFIDENTIAL

[back - break]

Page 6

99:25 101:14 104:24 110:1 113:1 144:16 150:17 151:25 173:21 175:2 180:14 188:14 206:12 231:10 235:18 backdoor 31:10 33:17 background 14:4 147:2 backgrounds 50:1 backup 92:18,24 93:8 balmy 185:5 bargain 154:8 bargained 154:10 barnes 5:7 based 69:11 86:4 102:19 103:15 104:3 114:11 122:8 141:8 143:17 177:18 217:19 219:22 232:1 basing 186:14,14 basis 18:10 26:10 31:17 78:16,25 79:4,6,12 111:24 bazan 3:11 bear 223:10 beginning 35:7 50:13 66:15 74:20 74:23 130:6 152:17 206:18 begins 74:10 113:1 180:14 206:12 235:18 behalf 12:20 24:4 24:5 25:20 26:2	44:8,10 209:13 behavior 157:19 157:21 believe 57:24 59:22 97:20 109:16 128:18 223:9 believes 109:8 beneficiaries 226:2 234:5 236:22 237:15 beneficiary 230:9 benefit 67:23 138:1 143:10 146:2,12 149:18 151:8 153:2,2 154:8 159:6 160:6 160:22 164:14 170:16 171:15 208:17 224:19 227:19 228:3 229:14 232:3,15 232:24 234:5,7,25 236:15,16 239:8 benefits 147:18,25 149:10 150:20 151:11 156:3,7,14 158:18,25 159:20 159:25 160:16 183:17 220:25 221:21 222:10 223:4 229:1 238:22 benjamin 184:21 185:5 bennett 48:7,13 49:25 50:1,3,7,15 61:16,18 62:3,24 63:2,12,24 64:15 64:17,25 65:13,16	bennett's 48:14 64:9 berne 7:2 bernstein 2:16 best 145:3 163:24 215:6,11 better 15:2,17 17:1 202:22 204:18,19 210:10 beyond 104:16 107:6 108:7 110:23 111:1,3,18 111:21,25 121:3 139:3 141:16 143:3 144:24 145:18 146:23 147:22 151:19 156:9 157:7 158:22 160:3 161:10 169:21 170:18 171:17 172:20 174:24 176:2 190:21 192:8 203:3,15 big 48:4 biggest 237:8 bilely 11:6 bill 72:21 billed 62:6 68:23 69:3,6,9,12,18,21 70:7 72:14,15,18 billings 48:16,17 48:21 bills 73:21,22 bily 7:8 binder 43:14,22 43:24 58:1,6 67:10,17 91:14,17 92:7,7,10 93:6 166:19,20,21,22	biopharmaceutical 14:22 15:1 bipc.com 4:19 5:3 bit 14:3 20:18 40:3 49:20 57:10 60:21 75:11 90:11 162:22 184:23 228:2 230:20 blackwell 4:14 blocker 8:13 167:7 blood 134:8,18,23 135:4,5 154:4 174:7 175:4 191:1 191:8 192:1 193:24 200:7 blown 227:17 bockius 3:17 bodies 161:8,22 body 40:18 bold 2:13 book 190:6 bosick 6:2 boston 6:14 14:6 14:10 15:19 28:7 52:19 73:14 bottle 175:24 177:4,7,12 bottom 76:6 163:14 169:1,2 bought 108:12 197:1,21 198:12 200:11 brand 132:13 199:12 branded 22:18,19 27:11 132:13 198:21 break 13:20 50:16 57:15 74:1,8 112:10 150:15 180:8,12 206:6,10
--	---	--	--

RESTRICTED CONFIDENTIAL

[break - cgpm]

Page 7

235:16 bresnahan 5:12 brian 62:4,5 bring 67:24 broad 22:13,20 62:15 broken 50:12 btlaw.com 5:8 buchanan 4:18 5:2 buckets 237:21 bullet 169:2,5,7,8 bunch 94:12 bush 39:12 business 14:10,11 14:14 20:6 21:14 21:22 24:8 27:3,6 busy 71:1,6,11 butcher 78:1 buy 195:8 196:24 199:8 214:7 buying 122:21 198:10 bye's 184:21 185:5	202:24 203:9,9 calculation 44:22 45:2,12,18 46:12 46:14 138:15 194:12,19 195:11 199:15 204:14 217:12 219:7 220:2 224:11 225:4 228:17 calculations 50:13 50:16,22,24 51:1 75:3 85:6 111:7 207:7 217:3 218:24 call 28:14 68:19 74:3 100:25 called 14:10,13 118:9 calling 53:2 calls 45:4 68:18 200:18 201:4 203:2 219:18 238:25 camp 2:24 campbell 5:13 cancer 39:13 185:6 226:19 capacities 35:16 capacity 17:20 35:13,24 61:13 134:17 capture 211:15 captures 211:17 car 195:5,6,7,8,9 225:10,12,16 carcinogen 163:8 163:10 carcinogens 163:17 cardinal 5:15	cards 221:18 care 71:5,18 carlo 5:19 carolina 5:4 carondelet 4:15 case 12:21 15:20 18:6,8,24 23:22 27:15 29:8,23,24 30:3,4,6,15 31:5 32:6 33:22 34:1 34:10,16,23 35:8 43:13 44:6 48:11 59:17 64:10,14,19 70:17 72:3 87:6 87:12,19,22 88:1,3 89:19 96:21 109:12 110:21 131:10 139:20 147:9,24 153:13 153:18 162:20 164:22 213:22 214:2 223:8 226:11,22 227:10 229:7 234:11 cases 17:24 18:1,3 18:4,4,5,8 24:9 25:12,13,17 26:16 26:19 29:21 31:11 33:18 cash 214:11 217:17 catastrophic 227:12,18 228:4 categories 41:23 217:19 category 22:20 239:11 cause 39:15 202:18 caused 26:18 154:2 234:9	caution 30:7 cdehart 5:20 cell 154:17 center 6:9 central 184:13 centre 3:19 6:4 century 184:16 certain 38:2,2,4,5 51:23,25 53:13 81:3 217:3 224:6 226:9 certainly 137:13 191:9 234:6 certificate 10:7 211:14 certified 1:15,15 certify 242:5,9 cetera 38:6 108:13 223:3 cgannon 6:8 cgmp 21:12 63:13 63:25 64:3,9 82:5 82:16 84:8,9 85:24 90:24 91:2 93:10,18 105:11 105:14,19,22 106:4,11,17,25 107:12,22 108:4 108:17,20 110:9 110:15,19 111:14 113:13 114:16 115:8,24 116:19 117:18 118:2,14 119:12,17 120:18 120:21 121:9,24 123:10 189:9 190:4,11 204:22 241:5 cgmps 108:14 cgpm 111:17
c c 2:1,23 3:1 4:1 5:1 6:1 7:1 11:15 242:1,1 c.whiteley 2:21 cabraser 2:16 calculate 46:6 50:22 194:22 203:25 206:20 220:9 231:19 calculated 46:8,9 200:24 202:1 203:10 207:3 216:17 220:9 227:23 calculates 204:8 calculating 45:8 47:20 200:24			

chain 106:20 107:10 108:11 115:22 132:20 182:17 201:22 235:22 236:17 chains 88:24 118:12 challenging 162:22 chance 67:7 change 66:7 244:4 244:7,10,13,16,19 changed 60:21 changes 243:10 245:6 changing 22:17 characterize 216:3 237:21 characterized 212:5 charging 34:25 35:1 charlotte 5:4 cheating 201:20 202:2,8,20 check 229:24 checked 73:23 181:6 checking 62:7 chemical 40:21 chemicals 39:14 39:19 42:2 43:7 chemistry 40:4 chicago 4:5 6:24 15:18 73:14 child 71:18 children's 217:21 chip 217:21 choose 192:17 christine 6:8	christopher 5:3 christopher.henry 5:3 chronic 81:24 82:2 82:21,23 83:2 chronological 59:23 cidra 41:25 42:16 42:22 cincinnati 7:4 circumspect 21:1 circumstances 224:7 citations 51:22,23 cite 124:17 126:8 212:5 cited 80:22 82:17 86:8 167:16,19 cities 71:17 citing 125:16 citizen 134:12 city 218:11,12 claim 25:9 claiming 25:10 claims 25:8 217:17 217:18 218:21 219:6 223:6 clarification 111:2 154:15 clarify 13:16 23:5 128:20 141:7 175:7 188:12 208:25 clarity 231:12 class 15:1,16 16:3 24:24 25:5,6 75:7 87:22 105:12 106:19 116:24 119:8,19,21 120:12,14 134:2,2 138:11 139:10	147:9,17 161:15 162:5 163:2 186:4 190:9 197:4,8,16 197:21 199:14 202:14 210:19 211:7,10,11,12 213:21 214:2,5,6 214:16,18 215:16 215:24 217:11,13 217:25 218:18 219:8 231:22 235:3 classes 75:4 111:8 cleaning 50:8 61:11 clear 100:8 110:11 187:11 209:20 clearly 100:5 150:4 153:23 clinical 133:7,11 133:14,15 146:18 148:12,14,18,25 185:20 234:9,11 close 49:7 closed 107:10 108:11 closely 48:7,9 50:10 coach 128:1 coan 6:13 code 65:22,24 66:8 codes 66:10 codified 121:6 cold 28:7 coleen 3:4 colleagues 51:7,10 collect 55:23 college 40:4 color 100:15 column 60:12	combination 216:10 combinations 218:16 come 23:4 27:19 42:8 58:11 74:4 135:25 204:22 comes 25:25 115:16 comfort 112:14 commencing 1:13 comment 51:8,11 51:19 comments 52:4 commercial 190:9 223:2,15,18 224:3 224:13 committee 16:2 29:8 30:14 44:13 commonly 65:24 communicating 176:11 communication 166:3 177:24 communications 165:25 166:14 171:4 172:4 174:3 177:21 companies 22:22 27:5,9,11,11,13 163:3 204:17 comparison 65:14 65:18 compensate 200:25 compensation 218:13 compensatory 200:16 competition 17:14 22:18,21,25 23:2
--	--	--	--

RESTRICTED CONFIDENTIAL

[competition - contaminated]

Page 9

38:23 39:2 competitor 210:8 complaint 75:7 79:7,13,15 80:22 80:25 81:17,20 82:15 83:7 89:23 90:22 91:12 92:17 92:19,19,23,24 93:4,4,8 94:7,8 97:24 103:23 111:14 complete 55:5 71:11 101:5,10,16 245:8 completed 243:17 completely 54:24 70:13 129:17 completion 38:17 compliance 106:17 compliant 108:17 116:19 152:2 201:18 241:5 complicated 116:21 complications 137:3 comply 70:17 compound 201:8 232:12 233:24 236:9 comprised 210:16 concept 189:5 concerned 71:13 concerns 173:6 conclude 81:7 99:22 100:24 concluded 241:15 conclusion 201:4 203:3 219:18 239:1	condition 106:21 174:13 175:15 conditional 107:13 107:14 conditions 22:24 23:18 137:12 191:9,10,13,25 193:25 conduct 121:12 conducted 133:11 133:14,16,18 confidential 1:8 31:1 confirm 205:7 confirming 124:1 conflicts 20:5 confused 63:16 120:22 confusing 87:1 conlee 2:21 28:13 59:13 connection 36:11 39:10 227:1 consent 11:25 consider 104:4 146:24 169:16 172:9 178:16,21 179:15 205:8 consideration 164:3,13 considered 104:14 104:18 105:6 117:17 146:3 170:10 190:5 205:14,19 226:24 considering 123:14,19 considers 103:24 consistent 143:20 158:15	construct 51:25 consultant 22:2 34:10 consulting 16:13 17:7 20:2 25:15 44:15 consume 162:2 consumed 108:12 consumer 24:24 25:5,6 39:20 114:3 119:9 124:22 137:19,25 141:4 146:20 150:22 151:13,13 151:17,17 152:4 152:10 157:4,17 157:21,23 158:20 158:20 159:25 160:1,18,18 164:13 190:1 193:1 198:11 199:1,4,8 205:8 209:25 210:17 211:19 212:6 214:10,23 215:25 221:16 225:2 229:20,22 230:2,7 consumers 24:15 25:9 75:4 105:24 106:7 111:9 124:10 125:3 127:9 128:25 131:5 132:25 133:1 136:6 140:8 140:15,22 141:10 141:15 145:13 149:17 150:20 151:11,15 152:11 153:7 156:4,6 157:2 158:19 159:20,23 160:16	160:21 163:6,8 164:3 166:14 170:16 171:9 172:24 174:4,9,15 176:12 177:22,24 178:3 179:2 180:4 184:14 191:7 192:20 193:19 194:13,25 195:1 195:18,21 196:8 196:23 198:21 200:25 202:17 204:6 205:15 208:16 209:8 212:10 214:15 216:15 222:14,22 222:24 223:16 224:17 225:7 227:24 230:13,17 231:3,15,20 234:4 234:7,25 consuming 233:6 233:6 234:5,7 consumption 185:20 contact 27:25 contacted 27:20 contain 176:8 212:6 contained 76:17 77:9 containing 173:16 175:5,7,18 contains 64:22 215:24 contaminants 154:9 240:1 contaminate 42:2 contaminated 42:13 153:25 154:6,11 169:25
---	---	--	--

RESTRICTED CONFIDENTIAL

[contaminated - court]

Page 10

171:19 172:8,9,12 173:19 179:23 187:16 194:14 197:20 199:13 200:12 202:13 contaminates 40:21 contamination 41:22 154:2 163:16 166:1 176:8 194:18 240:15 241:7 contents 10:1 context 124:15 151:8 152:7 157:19 233:17 contexts 16:10 84:6 212:3 conti 1:11 2:5 8:3 8:4,5,6,8,9,10,11 10:2 11:4 12:8,16 12:24 13:2 20:20 20:20 30:8 31:3 33:20,25 43:12,16 43:17 44:2 47:1 49:15 52:24,25 53:3,5,8,18 55:15 56:16,19,20,24 57:8,19,20 58:22 58:23 59:3 61:1 66:17 67:1,21 68:9,14,15,23 74:13,16,17 80:16 101:17 109:24 110:5 111:6,18 112:10 113:4 125:21 129:25,25 131:3 134:16 150:19 161:6 162:14 167:1,2,5,6 167:9,14 180:17	206:15 242:6 243:5 244:2,24 245:2,4,12 conti's 101:9 continue 55:15 100:7,23 162:21 169:9,18,18 172:25 174:17,21 175:12,25 177:15 178:4 179:3 continued 38:21 continuing 172:8 176:15 contract 236:20 237:12 238:22 239:7,13 contractual 236:5 236:14,19 237:3 237:10 238:3 control 141:9,15 143:10 174:13 237:3 controlled 141:2 controlling 141:22 142:25 193:24 converse 153:14 copies 63:8 243:14 copy 57:24 58:7 67:12 114:21 corporation 4:12 correct 16:17 25:17,21 38:12 47:13 59:25 60:7 61:17 66:22 67:1 67:21 68:9,10,16 68:17,24 69:4 72:15,16,16,19,20 73:7 75:8,15,16 77:19 78:12,23,24 81:2,15,17 82:19 84:2,23 87:19	90:12 92:9,11 93:5 103:2,8 114:15 116:13 122:10,18 130:2 142:17 147:9 164:4 168:24,24 205:24 207:25,25 209:3 213:8 222:4 222:15 242:7 245:8 corrected 184:2 corrections 245:6 correctly 169:12 169:15 201:23 cost 192:5 193:1,9 193:11 194:7 223:11 229:6,13 costco 66:2 costly 194:5 195:9 costs 136:11,18,24 148:1 149:10 156:14 158:25 183:18 194:17 221:17 council 39:13 counsel 2:5,10,14 2:19,25 3:8,14,21 4:6,12,17,21 5:5 5:10,15,22 6:5,11 6:15,20,25 7:5 11:10,25 12:12 13:9,9 28:2 29:3,7 30:24 33:13,25 34:16 35:9 44:6 52:4,16 53:20 54:1 59:16 64:13 64:18 67:23 73:18 76:3 79:22,22 80:3,10 90:6 92:11 94:16 100:1 100:3 111:3	127:13,20,21,25 128:1,5 155:4,12 155:22 180:18 181:2 197:3 206:19 219:3,23 220:6,8,14 232:2 242:10 243:14 count 204:19 counter 204:10 225:3 229:5,23 county 218:11,12 couple 13:25 19:21 coupon 221:17 course 15:5,6,14 16:9 70:20 157:12 164:19,22 courses 14:18,20 coursework 23:7 23:21 40:22 court 1:1,15 11:7 11:11,16 12:5,12 14:23 16:15 20:8 20:11 28:17,20 33:1,5 35:19 36:14 38:3 42:17 42:20 44:9 46:2 49:9 52:8 58:3 61:9 65:15 66:18 67:4 69:25 76:19 79:17,21 88:11 89:7 90:2,6,14 92:14 94:1 101:13 102:25 103:3 105:17 107:17,20 115:3,9 117:6 118:19 123:16 132:16 133:17 136:19,21,25 137:1 139:21 140:1,4 142:6,11
---	--	--	--

RESTRICTED CONFIDENTIAL

[court - deficiencies]

Page 11

146:21 150:3,9,11 151:14 152:12 153:22,24 154:14 154:22 166:23 170:3 171:23 184:22 191:18 192:3 195:1 204:6 204:24,25 205:2,4 205:21 207:14 208:2,10 209:14 211:11 212:8,16 212:18,20 219:1,9 225:20 228:7 230:21 235:6 courtesy 80:7 cover 226:2 230:24 coverage 17:14 224:9 228:5 239:8 covered 119:9 221:16 covering 238:23 covers 218:2 create 65:14,18 154:8,11 criminal 202:13 criteria 217:3,4 crowell 5:11 crowell.com 5:12 5:13 cs 243:15 culbertson 6:12 cull 46:11 cure 185:5 current 12:23 14:5 53:24 169:10 172:25 174:17 175:10,13,21,22 currently 14:17 29:15,20,22 30:1	curve 115:6 118:1 123:2,3,24,24 124:8,19 125:10 125:17 126:22,23 126:24 130:7,9,11 130:11,19 131:16 146:17 152:24,25 153:1 156:11,13 156:16,19 157:3 161:2,4 162:4 164:7,9,20,23,25 165:8 170:6,7 178:19 179:1,21 180:3,5 181:10,18 183:17 189:15 231:24 232:1 cut 55:6 132:17 cv 18:21,22 53:24 85:8,19 cvs 5:10 50:9 66:2 211:8 cwhill 3:4 d d 4:14,19 6:17 7:3 11:15 220:23 221:6,19,24 222:4 222:8,12,13 223:1 223:4,6,10,21 224:2,14,19 225:25 227:1,13 228:15 229:2 d'lesli 4:10 d.stanoch 2:22 dallas 4:11 damage 39:15 217:3 225:4 damages 44:23 45:2,8,12,18 46:6 46:9,9,12,15 47:20 50:13,16,20 75:4 75:17,19,22 111:8	194:11,22 197:24 199:15 200:16,16 200:23,24 202:1 202:24 203:10 204:1 206:20 207:2,4,19,21 208:22 209:2 213:22 217:11,13 220:1 231:20 dana 3:6 dangerous 154:9 184:18 dangerousness 154:2 daniel 5:13 data 46:1,6 47:20 50:8 51:1 54:7,9 61:8,10 62:7,9,12 62:13,16 63:6 65:9,23 207:13 209:2,7,10,13,22 210:2,12,13,15,24 212:1,2,4,25,25 213:1,6,9,20,23 214:2,3,9 215:3,6 215:15,20 216:2 217:1,14,20 datasets 217:17 date 20:24 34:11 53:24 64:8 69:6 244:24 245:12 david 2:22 59:13 davis 2:11,12 4:10 155:25 day 13:4,6 17:18 21:17,17 27:7 28:7 181:1 209:22 212:23 238:2 242:14 245:15 days 243:17	dc 3:13 4:20 5:14 dcampbell 5:13 dealing 71:16 dealt 141:18 death 135:24 deaths 135:24 decades 136:1 202:22 december 69:12 decided 192:16 declaration 8:10 46:25 47:6 48:24 50:12,14 74:14 77:7,7 declare 11:23 245:4 decreasing 22:18 deem 128:10 deemed 245:6 deems 95:25 99:2 103:7,11 defendant 3:21 4:6,17,21 5:5,15 6:11,15,20,25 7:5 24:7 81:24 87:25 88:3,16 90:19 91:1 206:23 defendant's 8:4 24:20,25 52:23 defendants 3:8,14 5:22 6:5 8:7 12:20 24:5 25:3 26:2 27:14 56:18 76:5 78:11 89:19,25 93:11,15,17 131:9 194:23 203:12 206:21 207:12 208:3,7,20 239:17 deficiencies 81:25 82:3,22 83:3 91:2 94:6
---	--	--	--

RESTRICTED CONFIDENTIAL

[deficiency - discussed]

Page 12

deficiency 90:23 define 36:7 77:23 217:11 232:24 defined 97:13 111:13 143:20 153:13,18 214:7 defines 122:8 223:15 definition 64:22 65:6 66:8 79:14 85:23 96:14,17 97:2,15 98:2,7,7 98:15,25 101:24 102:1,12,19 103:15,19 104:19 122:3,5,13 123:3,5 123:8,25 130:16 130:17 143:16 170:10 179:1 213:5 214:7 219:8 definitions 114:5 114:15,18 218:18 definitively 136:14 degree 115:16 216:4,6 dehart 5:19 delivery 188:18 demand 122:22 123:2,13,14,19,24 124:2,10 126:22 127:2 130:7,10,19 130:23 131:17 145:25 152:24,25 153:1 156:11,13 156:16 157:3,4,17 157:21 158:15,23 161:1,1 164:7,20 164:22 169:23 170:7 178:19 179:1,21 180:3,5	181:23 182:8,11 182:11,19 183:2 183:16 186:19 187:21 188:15 189:4,15 190:25 191:10 192:18 230:16 231:24 demonstrate 100:18 deny 176:20 department 14:9 218:8 depends 17:22 192:10 deponent 243:13 245:3 deposed 13:1 86:23 87:3,9 88:5 111:16 deposing 243:13 deposition 1:11 8:5,8 11:4,17,19 11:20 12:20 52:24 56:19 73:10 86:10 87:11,19,21,25 88:6 99:22 100:5 100:24 109:18 147:8 180:19 241:15 242:5 depositions 86:25 87:5,15 derives 81:23 describe 18:9 20:17 45:23 63:4 164:23 236:1 described 116:12 145:14 description 8:2 9:7 design 227:19	detail 20:18 56:25 detailed 79:13 80:21 89:22,23 90:18 detailing 89:25 details 21:6,10 30:12 50:25 90:23 91:1 deter 200:25 203:1 determinants 36:23 37:8,8 determination 81:1 determine 46:8 114:11 144:14 213:21 214:10 determines 37:24 determining 39:19 deterred 202:8 developed 15:19 16:2,9,9 23:21 developing 40:19 diet 198:4 differ 207:6 differed 160:18 difference 200:15 207:9 differences 236:23 different 19:13 24:8 60:13 64:23 65:7,10 69:19 74:25 86:5,6 91:2 104:3 117:24 128:21 135:6 150:22 157:24 158:9,20 159:25 160:24 161:7,18 161:20 169:11 173:2 174:19 175:16 192:12 193:2 196:9	198:12,12 199:1,3 205:9,10 206:20 206:22 207:4,9,17 208:1,5,9,13,19 212:3 235:22 236:5 239:4,16,16 differently 37:4 128:22 151:12,14 151:16 154:6 diovan 78:4 132:12 133:1 direct 184:11 226:16 227:7 228:19 directed 80:14 175:3 direction 52:2 83:17 directive 171:9 174:14 directly 226:12 237:14,25 239:6 director 14:12 disaggregate 213:24 disagree 33:21 59:8 disclose 20:25 30:20 disclosed 30:21 31:2 disclosing 31:10 disclosure 30:9 31:12 34:11 discontinue 165:19 166:9 171:10 172:17 discount 221:18 discuss 172:7 discussed 46:5 61:4 231:23
--	---	--	---

RESTRICTED CONFIDENTIAL

[discussing - drugs]

Page 13

discussing 27:22 33:12 47:19 152:8 discussion 50:21 76:25 91:24 94:19 discussions 53:20 60:2 disease 35:22 36:12 38:11,13 118:16 218:7 disincentivize 202:2 dispense 213:18 230:9 237:14 238:1 dispensed 118:11 213:4 224:23 239:6 240:23 dispenses 230:6 dispensing 38:1 dispute 131:21 138:17 156:5 disputes 20:6 21:22 24:8 27:4,6 disputing 156:15 dissertation 38:17 38:18,20 41:1,3,4 distinct 218:15 distinction 85:2,19 distinguish 85:13 distinguished 188:9 distracting 90:11 distributed 152:6 distributers 66:1 distribution 237:4 district 1:1,1 dlesli.davis 4:10 dna 39:15 doctor 46:3 54:10 54:10,18 65:15 132:17 133:8	143:24 149:24 154:14 157:13 165:20 169:10 171:11 172:8,19 173:1 174:10,18 174:22 175:14,15 176:1,14 177:16 178:6 184:22 191:19 207:15 document 1:4 53:7 53:10,12,13,17 56:10,13,17,24 57:19,23,23 58:5 58:14,14,21 59:2,3 59:7 63:8 66:17 67:12,24 83:18,25 85:18 90:17 167:6 167:13,15,16,24 170:20,22 172:23 173:25 documented 167:19 documenting 82:23 documents 9:6 46:13 50:6 55:24 56:7 64:16 69:17 82:15 84:18,21 86:7 89:24 90:25 91:4,7,14 92:18,20 93:18 94:5 167:18 167:20 180:25 doing 18:17 19:5,9 19:10,25 20:2 21:21 30:2 33:25 34:6 38:14 40:24 71:2 73:11,24 194:4 dollar 216:18 dollars 26:9	domain 24:11 donut 227:18 228:1 dorner 3:12 dorsey 6:17 dorsey.com 6:18 double 63:8 downright 185:11 downside 148:1 downstream 149:9 194:17 dozen 109:20 179:12 dr 8:5 12:16 13:2 20:20,20 30:8 31:3 33:20,25 43:12 47:1 52:24 53:8,18 55:15 56:24 57:8,19 61:1 66:17 67:1 67:21 68:9,14,15 68:23 74:13 80:16 101:9,17 109:24 110:5 111:6,18 112:10 113:4 125:21 129:25,25 131:3 134:16 150:19 161:6 162:14 167:5,14 180:17 206:15 draft 51:11 drafting 46:17 50:17 drafts 51:6 52:3 dramatically 135:25 182:12 drew 3:12 drill 111:17 214:22 215:16 drive 4:5 22:22	dropped 192:19 drug 16:1 22:5 81:8 89:10 95:25 96:16,20 97:14 98:3,6,16 99:3 103:7,11 104:4 110:16 113:22 114:8,18 115:13 116:3,20,22,23 117:17 118:10,17 118:20 119:7,16 119:21 121:7,21 122:3,20,20 123:5 123:6,8 124:6,6,25 125:17 126:3,16 127:10 130:15 133:12 134:2 145:20,21,22 149:19 151:6,8 157:5,23,24 177:15 184:7 185:7 189:10,22 190:8 195:17,20 196:2,9 198:3,12 199:1,3 200:1 205:10 220:25 221:20 222:9 223:4 224:19,23 226:3 229:1 230:16 232:6,18 233:4 239:25 240:13,14 241:3 drug's 116:1 drugs 5:22 22:3 35:21 37:6 38:12 41:12,17,24 65:7 66:10 79:10 103:15 104:2 105:2 111:11 113:11 114:23 115:17,22 118:8,8
--	--	---	--

RESTRICTED CONFIDENTIAL

[drugs - enumerating]

Page 14

118:9,25 119:1,18 120:12 121:8,9 123:4,25 125:11 126:1 131:20 132:14 133:3,7,12 133:13,19 134:2 136:2 152:3 153:25 154:6,11 156:15 158:16,24 163:2 178:20 184:15,18 190:5 197:7 201:1 202:14 203:13 209:25 210:25 211:4,4 218:2 226:9,18 227:16 231:18 233:7 235:1 236:17 237:15,22 238:2 239:7,9 dtdorner 3:12 duane 3:2,10 12:17 duanemorris.com 3:3,4,5,11,12 due 26:24 141:3 duly 12:9	87:16 111:11 114:24 115:5 124:7,17 125:7 126:14,23,25 127:1,5,6,15,16 130:1,10,21,24 131:18 137:22 140:8,15,21 141:3 141:23 142:2 143:1,6,11,12,16 143:19,20 144:4,9 144:23 145:7,7,9 145:13,23 146:15 146:19,23 149:3 151:23,23 152:8 152:16,18 153:6 153:11,14,14,18 156:12 182:7,25 183:12,13,24 184:1,3,7 185:10 185:17,25 186:1 186:10,12,15,19 187:21 188:15,16 189:8,11,18,21,23 194:17,19 195:12 195:15 197:1,23 198:6,22,25 199:4 199:19,20 203:25 204:5,7,8,14,23 208:7,18,18,22 225:8,14 233:19 economically 153:25 economics 39:22 125:13,15 126:19 188:20,23 189:2,6 189:15,19 economist 15:24 37:4 40:6 111:19 133:8 138:23	edits 51:19 effective 114:12 139:2,14 effectively 30:18 31:15 233:3,19 effects 154:10 efficacious 113:18 114:7 115:12 116:1,19 117:19 118:3,15 123:11 125:6 154:7 efficacy 36:21,22 37:2,7,13 113:13 113:25 114:5,10 114:16 190:13 eisenhower 2:8 either 20:6 21:22 50:9,15 60:20 88:12 149:5 152:21 191:25 195:24 226:12 227:13 elementary 189:6 189:19 eligible 222:25 223:17 ellie 4:9 ellie.norris 4:9 email 181:1,6 emphasis 120:7 emphasize 185:14 emphasizing 120:6 empirical 118:4 employed 222:23 employee 218:10 221:1,21 employees 48:8 87:25 encapsulated 183:16	ended 238:21 ends 74:7 112:22 180:10 235:14 english 28:22 enrichment 206:23 207:2,21 208:12 enrollees 223:11 ensure 110:13 120:2 121:9 entail 136:11 enter 22:23,25 39:1 106:18 107:12 108:10,15 119:8,18,21 120:6 120:12,14 161:14 162:5 190:9 197:15 entered 40:4 105:11 116:24 138:11 139:9 186:3 197:4,8,20 235:3 entering 188:6 entities 32:23 217:19 218:22 220:24 221:20 222:9,13 224:3 entitled 31:3 33:24 56:17 167:6 entries 59:20 60:25 entry 23:2 36:1,3 38:24 61:6 63:12 66:25 67:20 68:8 enumerated 101:24 102:4 enumerates 99:4 enumerating 85:11
e			
e 2:1,1 3:1,1,11 4:1 4:1,4 5:1,1,17 6:1 6:1 7:1,1 8:1 11:15,15 140:2 242:1,1 244:3,3,3 eabraham 5:19 earlier 60:4 62:22 171:3 early 40:20 easier 153:19 eastern 1:13 economic 25:9 44:15 75:7,15,22			

RESTRICTED CONFIDENTIAL

[equals - fails]

Page 15

equals 189:22 equivalent 78:4,6 equivalents 133:2 eric 5:18 erickson 48:7 61:16,18 62:24 errata 243:11,13 243:17 especially 26:25 40:25 esq 243:1 esquire 2:3,7,12 2:16,21,22,23 3:3 3:4,5,6,11,12,17 3:18 4:3,4,9,10,14 4:19 5:3,7,12,13 5:17,18,19 6:3,8 6:13,17,22,23 7:3 essential 33:17 established 111:6 111:23 establishes 152:1 estimate 50:20 et 38:6 108:13 223:3 243:4 244:1 245:1 evaluated 148:16 everybody 74:2 evidence 149:5 177:19 196:15 226:10 227:6 229:13 234:10 239:19 240:10 evidentiary 113:12 118:13 119:10,19,22 120:13,17,19,20 120:23,25 121:13 122:24 123:9 124:13 125:4 126:2,7 131:11	146:4,6,13 148:11 149:5 152:22 156:20 159:3 161:14 163:5 164:10 165:1,6 187:12 188:8 190:4,13 evolve 23:1 evolving 202:11 exact 49:11 128:19 exactly 28:25 43:2 49:21 122:11 160:6,22 223:25 230:4,10 examination 10:3 12:15 examined 12:9 example 172:22 222:21 225:12 227:12 exclude 216:18 217:17 218:12,23 220:16,16,23 221:1,18,21 222:7 excluded 219:7 221:15 excluding 153:6 218:21 219:6 exclusion 219:22 exclusions 218:19 excuse 30:19 32:14 54:23,23 73:9 80:2,2 90:6 149:11 152:12 154:24 155:15 206:4 214:5 executive 29:8 44:13 exercise 198:4 exforge 78:5 132:12 133:2	exhibit 8:2 43:17 52:25 53:14 56:20 58:16,22,23 74:17 166:24 167:2,5 exhibits 10:5 51:25 93:4 94:7 exist 130:8 156:12 225:17 existence 230:7 exists 124:23 expect 49:1 61:12 72:21 expected 38:24 expects 230:2,3 expenses 136:5 144:7,21 expensive 226:18 227:17 experience 25:16 26:24 38:24 83:23 83:23 84:15,20 85:4,14,22 86:5 133:6 151:11 153:1 experienced 156:5 156:7 experiences 160:24 expert 16:13 17:5 18:1,17 19:5,14,24 20:1,14 21:4,5,15 24:3,4 25:4,15 26:6,10 27:4 29:21 30:2 31:11 32:21 34:10 39:21 42:10 44:21 45:4 46:25 47:5 50:11 61:8 84:4 111:15 111:15 134:17 167:10 200:18	expertise 22:14,21 83:22 85:3 111:22 219:19 experts 23:17 34:11 87:16,18 88:3 191:12 expiration 38:25 explain 14:5 19:24 37:16 80:18 113:25 127:1 131:3 164:24 211:24,25 explained 230:14 explains 184:13 exposed 39:16 express 4:17 extensive 85:9 extent 23:1 30:8 39:2 45:4 201:4 219:18 238:25 external 237:12 f f 242:1 face 225:7 fact 102:17 105:21 105:23 170:6 176:9 212:6 241:6 factor 135:5 224:11 225:24 228:13,16 factors 22:16,22 102:4,14 103:12 103:23,24 104:4 104:12,14,20 facts 46:14 50:6 51:24 80:25 81:4 135:13 177:18 196:14 239:18 240:9 fails 243:19
--	--	---	---

RESTRICTED CONFIDENTIAL

[failure - form]

Page 16

failure 88:15 89:17 90:18 92:22 134:5 175:5 failures 82:5,8 93:10 fair 35:25 69:14 70:5 80:24 83:19 fairly 21:20 falanga 6:7 falkenberg 6:21 falkenbergives.c... 6:22,23 falls 182:11 familiar 37:1 39:7 40:5 165:10 167:13 189:5 223:5 236:4,13 far 109:19 fda 8:11 65:14,18 65:21 66:4 82:15 89:24 90:24 91:4 91:7,14 92:22 93:23 95:25 97:2 98:24 99:2 103:7 103:11,18,24 104:4,13 114:4,11 118:6,24 119:20 120:10 122:8 139:13 157:15 165:10,18,25 166:8,10,13 167:6 167:18 169:8 170:6,14 171:4,8 171:14 172:4,6,16 172:24,24 173:5 173:10,15 174:3,9 174:15,16,19 175:3,25 176:9,20 177:14,21,24 178:16 179:16 180:3 183:11,23	184:6,12 186:10 186:15,22 188:1 190:7 fda's 101:23 104:19 122:4 169:17 185:15 186:9 187:24 february 1:12 11:2 28:5,6 35:9 35:14 39:9 40:14 41:10 42:7 60:5 242:14 243:3 federal 121:5 152:1 184:17 217:18,22 218:22 221:1,21 224:4,12 226:1,13,25 227:7 228:14 229:10,11 fee 35:1,1 feel 26:22 73:23 101:11 fewer 26:19 fhs 6:3 field 23:17 figure 181:18,22 181:24 filibustering 100:6 100:9,19 fill 51:22,24 229:22 filled 184:19,24 185:3 final 46:18 finally 46:18 financing 15:8 21:18,23,25 32:10 32:23 finds 153:24 fine 20:22 55:8,10 55:20 95:6 109:16 206:7	finish 54:14 56:3 73:21 86:2 148:6 159:13 187:7 234:23 finished 26:4 38:18,20 41:3,4 86:19 159:8 187:17 finishing 40:23 firm 11:6,8 12:17 20:2 firms 15:10 20:7 20:10 24:9 39:1 89:5 first 12:8 18:23 22:14 24:21 27:25 28:1,9,10,13 29:4 35:16 44:12 56:23 58:5 59:12,22,23 60:2 63:12 66:16 69:23 79:8 81:22 107:12 146:16 166:6 169:5,7,7 185:17 187:5,19 217:14 221:5,13 fit 128:14 five 74:1 100:17 100:22 101:1 155:10,12 235:7 235:11 floor 3:19 6:4,9,14 focus 22:10,12 41:15 184:13 202:16 221:24 focused 41:10,14 194:12 199:20 200:11 231:11 focuses 14:15 focusing 123:14 123:20 221:5	folks 51:21 follow 67:13,14 201:7 221:11 232:11 233:9 238:18 followed 31:14 following 72:10 217:18 follows 12:10 184:15 218:15 food 22:5 89:10 96:16 97:14 98:3 98:6,16 110:16 113:22 114:8,18 115:13 116:3,20 118:10,17,20 121:7,21 122:3 123:6 130:15 145:20 185:7 239:25 240:14 241:3 footnote 75:8 76:14,14 77:14,14 77:15,15,18,18,22 77:23 79:8 218:19 footnotes 80:23 81:18 forced 198:22 foregoing 242:5 245:5 form 32:7 45:3 69:15 70:19 75:20 77:10,20 81:9,13 83:4 84:24 89:20 90:20 92:12 94:9 96:5,22 97:9,22 98:22 102:21 103:17 104:5,9 106:2,13 107:2,5 107:24 108:6,22 110:22 114:13
---	--	--	--

RESTRICTED CONFIDENTIAL

[form - going]

Page 17

115:19 116:7,14 117:11 119:3 121:2 122:25 125:19 126:17 127:8 128:12 130:3 131:1,23 132:9 137:20 138:3,19 139:3,16 140:9 141:24 143:2,14 144:24 145:17 147:21 148:20 149:20,23 150:23 151:18 153:9 156:8 157:7 158:1,21 163:11 163:21 164:5,16 165:13,22 169:20 170:17 171:12,16 172:20 173:13 174:23 176:2,21 177:17 178:11 181:13 182:23 184:8 186:16 192:8,14 193:3,13 193:21 194:9 195:22 196:4,13 200:3,17 202:4 203:2 205:11 207:24 215:18 216:20 219:17 220:10,17 222:17 223:13 224:5,15 226:4 227:3 228:18 230:19 231:5 232:8,20 233:5,21 234:13 237:6 238:7 239:18 240:8,21 formally 31:10 forming 178:17,22 179:16	forms 17:24 240:13 forth 51:6 73:13 84:22 fortunate 135:20 174:9 found 50:20 169:19 four 60:17,25 120:24,24 160:4 168:10 196:18 206:20 fourth 65:12 frame 55:2 frank 6:3 frankly 48:25 71:1 72:4 162:22 186:23 202:21 fraud 21:13 free 101:11 freeman 2:7 front 44:2 50:21 58:8 67:11 74:14 92:8 114:22 153:20 fulbright 4:8 full 51:23 101:3 163:5 204:8 207:22 function 189:4 fund 236:21 funding 224:4 further 11:21 65:12 154:11 242:9 future 200:21	gateway 6:9 gather 52:20 gathered 56:7 gcoan 6:13 geman 2:16 general 19:15 27:23 37:25 84:20 135:3 136:10 137:7 145:5 237:21 generally 18:9,12 19:22 36:24 37:1 38:10,11 39:18 45:23 48:9 61:19 62:5 63:1,5 84:11 85:14 135:13 158:24 173:5 207:11 generate 15:12 46:21 47:12 generated 26:5 35:4 45:22 generic 22:3,19,24 27:10 36:1 38:24 78:4,6 132:13 133:2 227:21 229:6 generics 229:13 geoffrey 6:13 geoppinger 7:3 germane 84:14,16 getting 216:13 gisleson 3:17 give 15:5,6 20:18 44:3 55:8 57:10 74:2,22 91:19 95:19,22,22 175:15 217:7 given 17:18,19 146:12 197:3 218:3 232:2 245:9	gives 173:1 174:18 giving 67:7,12 glaxo 42:18 glaxosmithkline 42:19,23 glenside 1:12 12:25 gma 62:25 69:20 gma's 44:7 go 32:15 39:3 43:14,22 48:18 57:5,11 60:12,17 60:23,24 62:19 65:12 66:3,16,24 68:5 73:25 76:5 76:21 81:19 88:7 91:20 95:1 99:5 114:20 126:20 131:3,25 141:16 150:11 151:25 152:14,14 154:5 159:13 160:12 173:21 175:12,17 176:14 178:5 195:6,9 198:22 208:14 231:10 237:14 241:11 goes 44:20 146:22 175:9 180:3 202:20 204:15,15 204:16 229:22 235:25 going 11:1 12:19 13:5,5 14:1 23:6 35:7 43:22,23 44:20 53:4 55:3 57:4,14 60:10 61:15 73:13 74:15 74:24 75:10 76:2 76:24 77:25,25 80:5 91:23 92:5,6
--	---	--	---

RESTRICTED CONFIDENTIAL

[going - guidance]

Page 18

94:14,15,16,18 95:5 112:22 117:16 129:7,10 129:11,13 144:2 144:17,18 150:14 161:25 162:11,12 175:2 180:10 188:14 201:11 206:9 208:21,23 215:10 220:22 235:14,24 241:14 gold 110:14 124:24 209:23 210:5 goldberg 3:3 10:4 12:14,15,17 15:4 16:16,20 20:16 21:7 29:1 30:13 30:24 31:18,23 32:3,11 33:7,21 34:14,21 36:5,17 38:7 43:10,11,19 44:11 45:9,19,21 46:19 47:2,5,14 49:13 52:14,22 53:4,6 54:13,15 55:10,17,22 56:10 56:12,16,22 57:11 57:18,22 58:11,17 58:21 59:1 61:14 61:24 62:1 66:14 66:20 67:9,15,25 68:2,4 70:8,21 71:12 73:25 74:5 74:12,19 75:23 76:21 77:4,17 78:8 79:22 80:1,3 80:10,15,17 81:10 81:14 82:18 83:1 83:9 85:16 87:4 88:13,14 89:15	90:9,16 91:3,20 92:3 93:1 94:4,14 95:4,8,13 96:18 97:4,17 98:9 99:7 99:11,13,17 100:1 100:3,23 102:2,15 102:23 103:4 104:1,6,23 105:20 106:10,23 107:3 107:21 108:3,18 109:1,5,10 110:17 111:1 112:1,5,11 113:3 114:19 115:14 116:4,10 117:8 118:5,23 119:14 120:4 121:16 123:12,18 126:12 127:4,13 127:14,20,25 128:5,11,15 129:2 129:5,9,12,19,24 130:22 131:19 132:4,22 133:20 134:14 135:7,14 136:4,12 137:8,24 138:16,24 139:11 140:6,13,19 141:1 141:11 142:22 143:6,8,23 144:5 144:11,17,19 145:11 147:5,15 148:4 149:13,21 150:7,18 151:4,16 153:4,16 154:18 155:5,21 156:1 157:1,10 158:7,17 159:4,12 160:7 161:5,17 162:8,20 163:18 164:1,11 165:9,17 166:5,17 166:25 167:4,10	167:12 168:2,7 170:13,21,23 171:13 172:14 173:9,20 175:20 176:17 177:1 178:7,14 179:5,9 179:14 180:7,16 180:24 181:8,16 183:8,22 186:7 187:4 189:7,20 191:5 192:4,11,24 193:7,16 194:6 195:13 196:1,7 197:5 198:7,24 199:24 200:14,22 201:9 202:5,23 203:8,20 204:2 205:6,17,23 206:1 206:7,14 207:18 208:11 209:16 210:4 211:22 212:24 213:17,19 214:20 215:2,8,14 216:5,22 219:4,15 219:24 220:7,13 220:21 222:18 224:1,10 225:23 226:23 228:9 229:17 231:1,8 232:14 233:1,14 234:1,18,20 235:9 235:20,23 237:16 238:12,19 239:14 240:3,16 241:9 goldberg's 20:21 gonna 52:23 76:5 93:12 141:6,7 good 12:16 55:20 63:23 74:5 112:10 113:16,17 138:6 210:25 235:7,9	goodness 210:4 gordon 6:2 gotten 150:20 government 20:13 20:14 21:3,9,15,24 22:7 24:13,14,16 26:3 32:22 71:3 105:4 162:7 165:2 186:5 190:15 217:19 218:22 219:15 220:1 224:4,12 226:2,13 226:14,25 227:8 228:14 229:10,11 government's 122:13 202:10 gpp 219:8 grateful 48:19 gray 28:7 great 43:25 95:19 112:12 142:12 217:10 greenberg 4:2 greg 4:4 greylock 8:9 16:14 16:16,23 17:4,8,11 17:21 18:14,18,24 19:18,25 20:5 27:21 28:1 29:11 34:23 44:14 48:8 48:18,20 49:23 51:8,11,18,21,21 52:16 59:6 64:17 70:9,14,16 gtlaw.com 4:3,4 guess 16:25 18:20 36:23 166:22 guidance 187:11
---	--	---	--

RESTRICTED CONFIDENTIAL

[h - honik]

Page 19

h	90:13 103:1	hilton 2:23 28:13	97:9,22 98:22
h 6:3 8:1 244:3	219:10 230:22	hinshaw 6:12	99:9,15,20 100:2
half 19:19,19	heard 79:25 80:7	hinshawlaw.com	100:21 101:1,16
69:24 70:2 109:20	128:4 150:3	6:13	102:7,21 103:17
112:16 221:14	213:12	historian 185:6	104:5,9 106:2,13
hand 242:14	hearing 12:5	hit 195:5,6,7,8	107:2,5,24 108:6
handful 63:1	147:1,2	hiv 218:6	108:22 109:3,7,15
73:11	heart 35:22 36:11	hold 46:16 49:17	110:3,22 111:5
handling 17:19	38:11,13 134:5,8	54:11 56:3 86:2	112:9,14,18
handy 57:25 58:7	134:19,21 135:8	86:14 91:5,9	114:13 115:19
hang 15:23 54:12	135:12,21,25	95:16,16 96:8	116:7,14 117:11
54:12,12,15,18	136:6,10 137:12	120:1 143:25	119:3 121:2
happened 173:8	137:17 175:5	148:6,15,15	122:25 125:19
happens 109:11	hebert 62:4	162:10,10 181:19	126:17 127:8,18
162:15	held 76:25 91:24	187:7 195:15	127:23 128:3,9,13
happily 111:5	94:19	219:10	128:17 129:4,7,10
happy 56:5 69:21	help 52:19	hole 227:18 228:1	129:14,22 130:3
69:22 91:18 99:5	helped 51:22,24	holes 210:19,21	131:1,23 132:9
126:20 196:20	51:25	home 177:7	134:9,25 135:10
hard 67:12 90:12	helpful 13:8 46:12	honan 62:20,21	135:17 136:8
114:21	50:7	63:3	137:5,20 138:3,19
harm 185:20	henry 5:3	honest 182:6	139:3,16,24 140:9
202:18 204:7,8	heparin 42:14	honik 2:2,3 20:20	140:16,23 141:24
234:9,11	hereto 245:7	28:12,23 30:7,16	142:8,12,15,19
harmful 40:22	hereunto 242:13	31:6,21,25 32:7,14	143:2,14 144:1,10
42:3 43:7 185:12	hetero 5:22,22	32:16 33:14 34:2	144:13,24 145:3
185:13	78:2 93:25	34:17 45:3,13	145:17 147:2,10
harms 39:16 43:4	high 22:17 134:8	46:23 47:3,7,10	147:21 148:20
185:16	134:18,23 135:4,5	52:6,11 53:2,18	149:20,23 150:1,5
harvard 15:18	174:7 175:4 189:3	54:13,23 55:11,20	150:10,23 151:18
23:24 40:23	191:1,8 192:1	57:7 58:20 61:20	152:14 153:9
health 5:15 16:23	193:24 200:7	67:22 68:1,3	154:24 155:15,23
39:15,20 40:22	highlighted	69:15 70:19 71:8	156:8 157:6 158:1
41:19 42:3 43:5,8	175:18	74:3 75:20 77:10	158:12,21 159:10
111:18 125:13,15	highly 30:25 50:4	77:20 79:19,24	160:2,19 161:9,23
140:8,14,21 144:7	55:13 114:3	80:2,5,13 81:9,13	163:11,21 164:5
144:21 217:21	124:22 189:25	82:10,24 83:4	164:16 165:13,22
218:10	190:1	84:24 86:19 88:20	166:11 167:9,11
healthcare 3:9,15	hill 3:4 5:17	89:20 90:20 92:12	169:20 170:17
hear 24:21 52:6	hillwallack.com	93:21 94:9,21	171:12,16 172:20
58:2,3 88:9,10,12	5:18,19,20	95:1,6,9 96:5,9,22	173:13 174:23

RESTRICTED CONFIDENTIAL

[honik - incurred]

Page 20

176:2,21 177:17 178:11,23 179:7 179:11,17 180:20 181:3,13 182:23 184:8 186:16 188:21,24 189:12 190:21 192:8,14 193:3,13,21 194:9 195:22 196:4,13 198:16 199:5 200:3,17 201:3 202:4 203:2,14,22 205:11 207:24 208:4 213:15 214:12,24 215:4,9 215:18 216:20 219:12,17 220:3 220:10,17 222:17 223:13 224:5,15 226:4 227:3 228:18 230:19,23 231:5 232:8,20 233:5,10,21 234:13 235:11 237:6 238:7,16,24 239:18 240:8,21 241:11 243:1 honiklaw.com 2:3 243:2 hopefully 14:2 hoping 27:1 hospital 217:23 hospitalization 135:9,16,23 hospitalized 135:12 hospitals 211:1 hour 60:11 72:14 72:15 112:17 182:10	hourly 35:1 49:15 49:19 60:11,12,16 60:19 hours 48:23 49:2,4 49:6,7 66:21,22 68:24 69:13,24 70:3,5,6 72:18,23 72:25 73:12 111:23 house 26:21 175:24 huahai 3:8,9,15,15 78:1 93:13 168:22 hudson 2:17 huh 20:11 41:8 201:16 217:9 human 39:15 40:22 41:19 42:3 43:4,8 148:23 149:14,15,16,22 163:8,10,17 humana 6:25 hunchuck 3:18 husch 4:14 huschblackwell.... 4:15 hyman 2:16 hyper 192:1 hypertension 38:10 133:24 134:3 137:3,16 139:2,15 141:3,9 141:16,22 142:25 170:9 172:3 174:8 190:20 191:1,8 192:1 193:20 198:3 199:18 200:7 hypothetical 158:3 177:9,18 196:14 198:17	199:6 235:5 240:9 240:22 i icu 211:6 idea 234:24 identification 31:15 43:18 53:1 56:21 58:24 74:18 167:3 identifies 65:22 identify 31:14 51:23 65:8,23 213:1,6,10 216:3 identifying 50:6 55:4 identity 121:11 122:4 ignorance 101:3 ii 8:12 167:7 illegal 124:11 illegitimate 124:11 162:3 183:19 196:3 199:9 202:12 204:18,21 230:14 231:3,14 illinois 4:5 6:24 ilyse 242:17 immaterial 200:10 immediately 103:6 immunology 226:19 impact 39:19 impair 13:24 implement 88:16 89:18 90:18 import 62:7 importance 126:7 important 19:8 importantly 111:21	imported 63:6 impossible 160:10 improper 129:6 158:2 196:14 198:17 199:6 240:22 impurity 203:13 inappropriate 240:9 incentivize 201:20 204:13 include 35:21 77:24 89:1 99:3 103:11 218:5,11 220:14 240:6 included 37:19 53:24 172:11,15 179:22 207:6 220:1,15 231:21 240:19 includes 42:13,14 78:3 178:8 179:1 217:13 218:18 222:21 including 15:20 77:8 78:9 85:5 178:20 191:14 194:4 219:6 221:17 inclusive 96:17 98:8,17 102:1,13 103:20,23 104:20 122:14 213:3,8 214:14,16,17 income 26:5,6 incorrect 213:11 incorrectly 93:12 increasing 22:17 increasingly 19:20 incurred 75:4 111:8
---	--	---	---

RESTRICTED CONFIDENTIAL

[independent - issue]

Page 21

independent 20:1 81:1 114:9 independently 20:3 81:7 index 10:5 indian 218:10 indiana 5:9 indianapolis 5:9 indicated 123:11 indication 118:16 indicative 37:13 individual 134:17 149:1 152:10,23 152:25 156:14 157:4,22 216:9 222:23 individualized 158:11 indulge 151:24 industries 4:7 industry 14:22 15:1,9,10,21 16:4 16:5,7,11,12,25 17:1,13 19:8 21:20,22 22:16 23:9,10,11,17,19 27:8 32:9,25 33:4 33:10 34:7 41:20 42:11 83:24 84:5 84:12 85:4,10,14 98:1 105:7 186:24 187:9 210:6 industry's 188:5 202:21 infectious 218:7 information 34:12 52:20 56:7 informed 134:13 informs 85:5,22 86:7	infused 218:2 ingersoll 4:18 5:2 initial 89:11 injected 218:2 injured 199:10 225:10,15 injury 75:4,13,14 75:15,22 111:8 154:12 194:12,22 195:4,5,16 196:21 196:24 197:19 198:2,8,10 199:4 224:25 225:18,21 227:14 innovate 15:11 innovation 14:16 inpatient 211:5 input 52:17 inspection 92:21 instance 119:15 instances 89:16 institute 14:12,12 14:13,14 instruct 13:11 20:21 30:16 31:21 31:25 33:14 instructed 31:9,13 209:12 instructing 169:8 169:17 177:14 instruction 55:8 209:17 219:3,23 220:5 instructions 9:3 insurance 209:8 211:16 212:7,8,13 217:15,21 218:1,4 218:8,9 221:16 222:24 223:15,16 224:9,21 225:1 227:22 229:24	230:7,8 237:4 insure 157:14 insured 24:15 108:12 200:12 223:19,22,24 insured's 232:5,17 insureds 233:3,19 insurer 119:10 157:14 223:18,20 230:3 insurers 106:8 195:3 197:22,22 221:2,23 222:3 223:2 239:6 intellectual 19:4,6 intended 133:24 134:3,4 202:1 intense 71:19 intensely 71:2 72:1,2 intently 48:1 interest 35:17 36:11 interested 27:22 37:5 38:23 39:18 40:25 43:2 242:11 interfere 128:2,15 interfering 100:4 interject 54:14 interjected 142:16 interrupt 71:8 80:4,4 86:20 99:9 99:10,15 109:17 127:21 144:1 162:18 188:10,11 interrupted 109:9 159:16 160:10 234:21 interrupting 67:6 96:10 99:13,21 109:3,17 179:7,8	interruption 128:7 142:4 investigating 21:12,12,13 investigation 21:11,16 investigations 21:3,9 invoice 35:4 49:22 59:12 63:9,20 66:25 67:3,17 68:9,11,14,16,22 69:1,5,7,9,23 70:4 72:6,7,11,12 invoiced 66:21 68:15 invoices 8:9 59:6 59:20 62:20 69:11 70:7,10,16,23,24 71:22 involve 41:24 175:10 involved 17:15 20:15 22:4 30:4 30:15 33:19 34:6 34:10 48:21 133:15 involvement 20:25 31:11 iqvia 63:6 65:18 65:23 209:3,22 210:2,12 212:25 213:20,20,23 214:3,9 215:15 216:2 217:1 iqvia's 215:20 irbesartan 1:3 8:14 issue 64:7 65:6 66:10 76:4,11,15 77:6,13,23 78:9
---	--	--	---

RESTRICTED CONFIDENTIAL

[issue - leaving]

Page 22

81:5 82:1,6 83:7 91:16 96:25 97:7 97:12,21 102:5,5 130:13 133:3 138:9 139:8 144:8 144:22 147:19 151:12 152:9,19 153:8 156:4,6 157:21 158:19 159:23 160:17,22 164:4,21 165:4 169:9 170:15 171:15 172:16,17 172:18 173:11 174:20 175:23 176:19 177:5,13 178:20 179:3,4,23 182:15 190:17 193:18 196:10 198:10 199:2 200:13 205:16 211:3,9,13 215:17 225:3 226:11 227:9,16 229:6 230:12,15 231:14 231:18 232:5,17 233:20 234:16 236:7 237:4 238:5 238:15,23 239:23 241:1,7 issues 14:15 44:15 44:22 158:11 italics 185:15 items 56:4 ives 6:21,22	janow 4:19 january 59:24 60:6 239:23 jdavis 2:12 jeffrey 7:3 jersey 1:1 2:9 5:21 6:10 jgeoppinger 7:3 job 39:23 66:6 67:8 john 2:12 3:17 155:25 156:2 185:6 john.gisleson 3:18 jonathan 4:19 jonathan.janow 4:19 judge 100:7,25 153:13,17 judge's 155:13 judged 114:7 115:11 116:20,22 117:3 146:9 july 72:2 167:24 168:6,11 171:1,1 173:22 174:15 176:10 177:4,4,11 177:12 240:20 justified 153:12 justin 7:8 11:6 95:10	keep 120:10 176:20 238:5,10 239:13 kid 71:5 killer 184:20 185:4 kind 21:20 37:10 38:15 39:22 50:13 50:22 143:10 162:15 221:4,14 233:10 kinds 17:10 20:19 kirstin 6:22 klinges 3:6 knepper 4:14 know 17:18 19:13 21:13 23:8 26:21 29:11,14,25 31:3 33:22,23,24 34:9,9 35:3 40:5 41:13 42:11 44:19 48:10 48:15 60:4,15 62:8,11,18 63:2,4 63:15 64:2,3,7,9 64:21 67:2 78:18 85:23 86:3 93:15 111:19 114:21 123:21 127:3 129:4 131:6 134:6 138:21,22 146:11 158:5 163:24 181:7 192:18 195:3 200:4,15 210:1,9,11,23 216:7 224:2 227:22 229:3 238:17 239:12 knowledge 84:20 207:8 known 29:3 163:16 166:2	188:5 209:23 212:4 240:1 knows 125:3 126:11 l l.l.c. 2:20 label 65:25 66:1 120:3 laboratories 6:5 labs 5:22 lantech 93:25 94:3 lapses 42:12,24 43:3,5 largely 16:24 19:19 20:6 24:8,9 24:14,18 25:1 45:17 50:5,7 211:4 226:7 launch 107:13,14 107:14 108:14 110:10 law 12:17 14:9,15 121:5 152:1 law.com 2:21,22 2:23 lawfully 152:5,5 lawsuit 127:18 lawyer 200:20 203:15 lawyers 28:8 29:12,16,22 30:3 30:14 31:4,14 layne 2:23 28:13 lbresnahan 5:12 lchb.com 2:17 lead 22:16 134:8 134:19,24 learned 193:22 leave 208:23 leaving 84:19 132:6 207:20
	k		
	k 3:17 4:20 kanner 2:20,21,22 2:23 kapke 5:7 kara 5:7 kara.kapke 5:8 katz 2:7 kbi 6:22		
j 2:16,22 5:12,19 jamie 1:14 11:8 52:7 144:13,16 150:2,10 152:17 219:13 242:3,17			

208:12 left 134:7,18,23 legal 7:8 17:16 45:4 105:12 121:10 200:18 201:4 203:3 219:18 238:25 243:23 legally 88:23 legitimate 105:5,7 105:8,23 106:1,12 107:1,23 108:5 115:6 118:1 121:15 124:8,18 125:17 126:24 130:9,11,19 131:16 146:3,16 148:2,9 152:4 156:22 159:1 161:2,4 162:4 163:2 164:9,25 170:5 181:10,12 182:5,5,22 183:5 186:25 187:11,13 188:7,17 189:10 189:16,17,22 197:4 202:19 209:24 210:17,18 211:19,20 231:17 232:1 legitimizing 180:2 legitimized 181:23 legitimize 201:20 letters 93:23 level 109:21 216:14 levels 235:22 239:16 lewis 3:17	lhilton 2:23 liability 1:3 18:4,6 18:8,11 19:16,19 19:21 24:23 25:4 25:13,16,22 31:20 46:7 75:18 206:21 206:22 207:5,10 207:20 208:7 license 89:11 242:17 lieff 2:16 lieu 11:21 life 200:21 liked 86:24 87:8 limit 217:14 227:12 228:4 limitations 210:2 210:5 211:25 212:3 limited 5:22,22 6:6 89:2 99:3 102:13 103:12 limiting 76:16 line 9:4,7,10,13 65:13 88:15 163:14 174:2 244:4,7,10,13,16 244:19 lines 81:22 list 54:3 65:21 66:4 70:12 73:18 85:9 173:16 listed 69:18,20 76:14 77:14 81:18 84:2,14 89:24 92:18,19 96:4 98:7,20 101:25 103:12,20 104:7,7 104:8,21 217:5 listen 92:4	listing 72:24 lists 96:14 literally 189:2 literature 40:19 126:6 litigated 32:1 litigation 1:3 11:5 16:24 17:6,8,11 19:10 20:23 26:25 little 14:3 20:18 40:2 41:7 49:20 57:10 60:21 63:16 75:11 90:11 162:22 181:5 184:23 228:2 230:20 live 157:18 livenote 1:15 llc 2:2 3:9,15 4:21 5:5 llp 2:11,16 3:2,10 3:17 4:2,8 5:7,11 5:17 6:2,7,12,17 6:21 7:2 located 216:7 long 21:18 22:5 41:21 46:20 47:10 50:10 116:21 174:2 longer 64:21 longstanding 35:17 look 49:17 56:25 57:4 72:6 78:19 78:19 83:13 103:5 113:4 121:4 149:14 209:22 214:9 looked 62:9,16 84:1 93:3,19,20	looking 36:20 59:21 67:16 69:1 81:23 91:10 97:18 105:1 134:15 209:18 looks 26:10 59:21 59:23 60:5,11,16 62:6 66:21 69:23 losartan 1:2 8:13 243:4 244:1 245:1 loss 25:9 195:15 197:1,23 198:6 200:25 208:18 225:14 losses 185:17 lost 101:17,19 184:23 lostless 194:4 lot 22:6,6 36:2 47:18,18,22 48:14 71:2 84:6,9 85:24 86:3 137:10 183:14 230:11 232:12 233:23,24 lots 46:17 51:6 141:14,15 loud 54:20 louis 4:16 louisiana 2:24 low 163:7 229:6 229:13 lowering 154:4 luke 5:12 lunch 112:10,24 m m 1:11 2:5,7 4:3 4:10 5:7 6:13 10:2 140:2,2 242:6 madam 109:23 maintains 124:24
--	--	--	---

RESTRICTED CONFIDENTIAL

[major - mckinnon]

Page 24

major 40:4 majority 71:16 73:5 228:25 makeup 19:13 making 85:3,19 201:1 233:25 manage 192:16 managed 198:3 management 193:5,6 manager 238:22 managers 236:15 236:16 239:8 managing 71:4 mandates 121:7 manipulation 50:8 61:11 manner 12:2 109:8 116:18 128:14 228:20 mansplaining 162:21 234:22 manufactured 76:4 77:24 78:10 113:16 115:24 121:23 191:15 241:4 manufacturer 108:20,25 110:13 110:20 115:23 117:19 119:9,23 119:25 120:1,11 123:7 124:13 125:1 126:10 159:2 171:22,24 171:25 190:12 206:21 209:1,5 212:14 218:16 239:17 manufacturers 15:11 36:3 64:6	64:23 65:8,9,11 81:24 82:7,16 84:7 88:16,22 90:19 91:1,15 92:23 93:19 105:5 106:16 107:9 108:9 110:7 116:16,25 126:3 131:9 163:15 171:5 197:15 198:20 201:1,21 202:2,8,12 203:1 203:12,18 210:20 239:24 240:12 241:1 manufacturing 42:12,25 62:7,8,12 81:25 82:6 91:5 110:14 113:16,17 116:2 121:24 125:5 203:12 march 28:6 35:10 35:15 39:9 60:5 mark 30:24 43:15 52:23 74:15 166:25 marked 9:12 43:17 44:2 49:15 52:25 53:5 56:20 57:20 58:23 59:3 74:15,17 167:2 market 2:4 22:19 36:4,7,8,9 37:19 40:3 63:13,25 64:4,9 65:3 66:5 86:4,6 89:12 107:13 108:15 113:14,20 116:18 117:16 120:17 126:1,11 131:14 132:14 145:25	146:8 148:7,10 174:8 185:2 186:6 187:2,15 191:3 198:11 202:19 204:23 209:25 210:8 211:20 222:24 marketed 78:3,5 marketplace 184:19,24 185:3 190:2 194:24 markets 14:9 22:23,24,25 36:1 38:6 39:1 114:4 124:22 210:8 marking 56:16 58:22 167:5 massachusetts 6:14 match 66:10 material 93:8 229:12 materials 15:20 16:8 23:8,22 46:11 54:4 83:15 83:20 84:13 85:11 85:15,18,20,22 91:10 math 211:14 matt.knepper 4:15 matter 11:24 18:5 19:15 21:11 27:18 27:19,24 28:11 29:9,13,17 31:2,5 31:16,19,20,24 32:1,2,4,9 33:9,11 34:25 35:2,5 45:8 45:17,22 46:7 48:5,13,15,18 60:6 62:25 64:7 66:11	69:13 70:12 73:9 75:5,6,13,15 81:5 83:8,23 84:15,19 84:22 85:7,12 111:9 130:12 135:4 136:10 137:7 138:14 143:17 145:6 148:13 151:3 152:20 160:25 163:14 182:6,25 183:6 186:18 187:21 198:13,14 200:13 203:25 204:18 231:20 239:15 240:4,17 mattered 196:11 matters 16:24 17:16,17,19 19:1,6 19:14,17 20:4,12 20:19,22 21:8 24:9,18,24,24 25:2 25:23 27:9,14 29:15,17 30:9 34:1,5 117:14 matthew 4:14 maz 6:23 mazie 2:7 mazieslater.com 2:8 mckesson 4:12 mckinnon 8:9 16:14,16,23 17:4,8 17:11 18:14,18,24 19:18,25 20:5 27:21 29:11 34:23 44:14 48:8 51:8 51:11,18,21 52:16 59:6 64:17 70:9 70:14,16
---	---	--	---

RESTRICTED CONFIDENTIAL

[mdl - misbranded]

Page 25

mdl 1:2 mean 18:13 19:2 23:12 24:12 25:6 26:11 29:19 30:1 36:7,18 41:13 47:24 51:3,4 64:11,15,20 67:2 70:24,24 73:20 76:11 78:18 82:2 85:1,23 87:7 89:13 92:16 105:8 105:10 111:4 113:10,25 114:6 115:1,2,3,5 117:22 119:20 120:8,14 120:16 121:13,19 122:1,2 123:22 126:5 134:1,11 135:19 137:13 141:8,14 142:1 143:6,13 145:5 157:12,17 158:6 158:14 162:13,14 165:16 168:5,22 173:25 176:23 177:2 185:10,12 193:4,23 198:18 203:17 204:4 207:11 210:23 214:5,5,24,25 215:1 221:8,9,11 232:23 234:17 236:11 237:20 238:11 239:13 meaning 117:22 meaningless 148:18 means 63:15 97:3 105:13 meant 62:11 64:3 64:8 184:1	measure 207:3,19 207:21 208:7 media 11:3 74:7 74:10 112:22 113:1 180:10,14 206:12 235:14,18 medical 136:5 154:4 218:3 225:13 medically 154:7 medicare 217:22 217:23 218:1 220:23 221:6,6,19 221:24 222:4,8,12 222:13,25 223:1,6 223:10,17 224:14 225:25 227:1 228:15 medication 172:25 175:13 190:20 193:2,12,20 194:8 medications 13:23 175:19 192:7 medicine 169:10 169:18 174:17 175:21,22 meet 84:8,8 105:11,14,19 107:12 108:13 113:15,20 115:7 116:25 118:13 119:10,12,16 121:9 122:23 123:4,8 125:4 126:2 130:20,23 145:25 146:4,6 148:10 149:4,5 156:20 161:13 163:4 164:10 165:1,5 186:20 187:22 188:8	190:4,12 204:22 meeting 28:10 29:4 35:9 110:9 114:16 119:19,22 119:23 120:13,17 120:19 123:9 125:8 126:23 131:11,17 146:20 152:21 159:3 182:19 meetings 28:1 meets 121:24 123:7 146:13,15 187:12 megan 6:23 member 134:1 214:5 215:16,25 236:16 member's 213:21 214:2 members 21:22 54:8 201:21 214:6 214:16,18 menacing 184:18 184:19 185:2,3 mention 68:17 86:22 mentioned 48:4 51:5 62:21 216:23 229:19 merely 111:16 meridian 5:8 messages 180:18 met 23:20 28:9,10 113:12 124:13 130:8 217:3 methodology 164:2 methods 211:21 211:23	microbe 184:20 185:4 microphone 75:11 152:13 mid 159:16 160:11 middle 50:23 55:12,12 99:21,23 105:2 142:17 mike 61:2,3,6,7,8 military 218:7,8,9 mind 25:25 206:6 minimized 202:15 minimum 115:25 119:12,16 120:18 185:8 190:11 241:5 minute 74:1,2 180:8 181:19,19 minutes 74:4 155:10,12 235:7 misbranded 76:8 78:16,23 79:14 95:25 96:13,21 97:1,2,13,13,25 98:5,14,25 99:3 101:22,22 102:1 102:11,12 104:15 104:19 105:3 111:12 114:24 118:15 122:12 124:9,20 130:14 130:18 131:7,15 132:3 133:4 138:10 139:8 152:3 165:7 170:1 171:20 173:19 179:24 182:16,16 183:4,19 184:15 185:16,19,21 186:3 187:2,15 194:14,23 197:12
--	--	--	--

RESTRICTED CONFIDENTIAL

[misbranded - notice]

Page 26

197:13 199:9,22 200:12 202:13 231:17 234:8 misbranding 79:13 80:21 81:4 84:11 96:15 97:19 98:2,11,15,21 102:4,18,19,20 201:2 mischaracterizat... 51:9,13 77:22 96:24 188:13 mischaracterized 116:8 mischaracterizes 189:13 mischaracterizing 50:19 188:3 misconduct 204:1 mishear 213:17 misheard 213:13 misremembering 28:16,19,20,21 missouri 4:16 misunderstanding 151:21,22 mitigate 191:25 mitigation 89:2 mix 18:10,24 19:22 222:3 mixing 233:10 modalities 199:17 model 182:10 183:20 moment 139:6,19 139:19,22,23,24 140:1,2 147:23 149:11,12 151:2 153:3 160:25 161:13 162:2 163:1,13 194:18	195:11 196:25 198:5 199:18 203:23,24 225:7 225:18 money 34:15 136:18,24 144:6 144:20 145:6 monroe 6:24 month 28:3,4 209:5,9 212:14 214:18 215:21 216:9 218:17 months 47:16,17 47:23,23 71:6 morgan 3:17 morganlewis.com 3:18,19 moring 5:11 morning 12:16 13:24 147:13 morris 3:2,10 12:17 moskowitz 1:14 11:8 80:7 99:24 101:12 242:3,17 mother 71:4,17,24 73:15 135:11 223:17 225:11 229:2 move 34:13 80:9 128:23 moving 201:11,13 206:2,5 mulberry 6:9 multiple 64:6 93:24 153:12 165:25 166:14 murtha 5:17 mute 152:13 muted 142:21	mylan 6:5,6 42:1 42:15 78:2 93:24 mystery 51:15 n n 2:1 3:1,18 4:1 5:1 6:1 7:1 11:15 140:2 name 12:16,22 33:22 78:1,4,5 93:15 216:9 name's 11:6 names 33:23 60:24 217:20 national 15:25 38:1 65:9 66:11 209:4,7 217:15 nature 36:12 43:4 ndc 65:22,23 66:3 66:8,10 ndcs 65:14,17,18 65:19 ndea 40:9,16 41:11,17 76:17 77:9 239:17 ndma 40:8,16 41:11,17 42:4,6,7 42:8 76:17 77:9 177:8,13 239:16 nearly 31:9 57:7 necessary 204:11 245:6 need 13:20 33:22 33:23 43:14 54:17 54:18 79:23 84:8 95:2 109:14 125:9 146:6 157:23,24 158:6 202:25 needed 190:19 needs 66:6 75:11 111:19 115:23 128:3 182:8	219:12 229:25 neither 105:3 242:9 never 154:10,13 186:3 new 1:1 2:9,18,18 2:24 5:21 6:10,19 6:19 73:14,16 166:24 195:8 newark 6:10 nitrosamines 39:6 39:7,11,25 43:6 240:1,7,18 241:7 noise 147:3 non 113:9,10 152:2 172:9,10 176:24 191:16,24 201:18,18 223:23 noncompliance 201:21 202:3,9 noncontroversial 80:8 nonzero 204:12,16 normal 20:24 norris 4:9 north 5:4 norton 4:8 nortonrosefulbri... 4:9,10 notably 15:10 171:21 notary 242:4 245:13,19 note 218:14 243:10 noted 11:10 110:3 245:7 notes 242:8 notice 8:4,7 52:24 56:18
---	--	--	--

RESTRICTED CONFIDENTIAL

[notices - okay]

Page 27

notices 92:22 notion 124:18 125:16 126:15 novartis 172:1 191:15 199:12 november 45:23 47:3 number 8:2 11:3 15:22 20:4 37:12 50:19 54:3 74:7 74:10 88:25 112:22 113:1 170:25 180:14 206:12 235:14,18 numbers 51:25 nw 3:13 5:14 ny 243:15	139:3,16 140:9 143:2,14 144:24 145:17 147:21 148:20 149:20,23 150:23 151:18 153:9 156:8 157:6 157:6 158:1,21 163:11,21 164:5 164:16 165:13,22 169:20 170:17 171:12,16 172:20 173:13 176:2,21 177:17,17 178:11 181:13 182:23 186:16 192:8,14 193:3,13,21 194:9 195:22 196:4,13 200:3,17 202:4 203:2 205:11 207:24 215:18 216:20 219:17,17 220:17 222:17 223:13 224:5,15 226:4 227:3 228:18 230:19 231:5 232:8,20 233:5,21 234:13 237:6 238:7 239:18 240:8,21 objected 31:8 objection 13:12 32:17 34:18 45:13 53:19 55:9,17 61:20 82:10,24 88:20 96:22 102:7 110:4 111:24 128:8,8,12 129:19 129:20 134:9,25 135:10,17 136:8 137:5 140:16,23 141:5,24 142:9	147:10 154:25 155:16,24 158:12 160:2,19 161:9,23 166:11 174:23 178:23 179:11,17 181:3 184:8 188:21 189:12 190:21 198:16 199:5 201:3 203:14,22 214:12 220:3,10 238:16 238:24 objections 8:6 12:1,3,6 13:10 56:17 observation 34:4 obtain 52:4 210:12 210:14 obtained 208:16 obviously 19:7 24:13 148:23 occur 98:11 230:5 occurred 42:25 88:6 97:7 154:13 194:13 196:25 197:25 227:15 occurrence 40:8 40:16 41:11,16,18 occurs 195:4,5,15 196:21 197:19 218:15 224:25 225:18,21 october 72:19 offer 220:25 221:20 222:9 224:14 225:25 offered 80:8 offering 228:15 offerings 222:14 office 22:3 218:3	oh 16:8 73:2 159:17 201:14 210:4 218:17 ohio 7:4 oils 185:5 okay 12:12 13:1 13:12,18,22 14:2 16:22 18:3,16,20 19:18 24:2 26:4 26:13 30:2 35:7 37:10,16 40:10 43:20,25 44:5 47:16 50:18 51:5 51:14,20 56:8,9 58:9 59:14 60:4 60:22 61:5 63:12 63:23 67:9,20 74:4,23 78:19,21 81:21 82:21 84:17 90:14 92:6 93:2 93:16 94:11 95:1 95:9,19,23 98:24 106:24 107:20 108:24 112:7 113:7 116:15 117:13 120:5 121:4 122:6 130:5 132:23 134:15 141:20 142:12,19 143:15 145:19 147:4,4,16 148:22 150:1,5 151:20 159:17 161:25 162:13,24 166:13 168:13,14,25 169:1 176:1,18 177:3,8,9,10 180:8 181:9 189:14 191:7 196:2,8 197:6,18 201:14 208:21 213:17
o			
o 11:15 140:2 o'clock 241:10,14 241:16 o'reilly 6:7 oath 11:22 object 32:7 45:3 69:15 70:19 75:20 77:10,20 81:9,13 83:4 84:24 89:20 90:20 92:12 94:9 96:5 97:9,22 98:22 102:21 103:17 104:5,9 106:2,13 107:2,5 107:24 108:6,22 110:22 114:13 115:19 116:7,14 117:11 119:3 121:2 122:25 125:19 126:17 127:8 130:3 131:1 131:23 132:9 137:20 138:3,19			

RESTRICTED CONFIDENTIAL

[okay - parts]

Page 28

217:10 221:25 223:14 231:10 234:20 235:11 236:13 ones 77:14 83:6 84:14 87:8 179:22 226:12 opinion 32:5,5 45:5 75:25 138:22 138:23 151:9 153:3,7,20 154:21 154:23 155:3,3,13 155:20 156:17,18 178:17,22 179:16 179:20 183:9 194:2 200:19 201:25 opinions 65:5 75:3 75:18,19,21 83:21 84:1,19,22 85:5 86:11 87:6 111:7 151:2 152:20 160:25 163:14 203:24 opposed 223:18 option 169:12 173:3 174:19 175:16 options 192:22 optumrx 6:20 orange 190:6 oranges 233:11 order 56:5 59:23 66:3 84:8 106:18 115:21 123:6 182:7 190:8 227:24 228:2 231:19 organization 15:8 21:19,23 22:1 32:24	orleans 2:24 osfeldg 4:4 ostfeld 4:4 outcome 242:11 outcomes 140:8,15 140:20,21 outlined 79:7,15 79:15,17 81:17 82:14 110:15 111:13 outlines 27:23 outside 18:18 31:2 52:15 102:8 106:13 134:9,25 137:5 138:4,20 139:16 140:10 141:25 148:17 150:23 157:18 158:2 163:11 165:14,23 193:14 200:18 234:14 238:7 overlapped 38:16 overlea 12:24 owned 42:22 oxford 3:19 6:4 p p 2:1,1 3:1,1 4:1,1 5:1,1 6:1,1 7:1,1 11:15 p.m. 112:9 241:16 pa 12:25 packet 72:7,12 page 8:2 9:1,4,7,10 9:13 10:4,5,7,8 53:15,15 57:1,9 59:12,22 63:7,19 66:16 95:17 104:25 151:25 168:8,9,14,17 169:1 184:15	217:10 235:25,25 244:4,7,10,13,16 244:19 pages 57:3 60:17 68:6,7 168:3,4,4 168:10,11 227:13 paid 105:6 127:6,9 127:9,16 130:1,24 181:12 182:4,21 193:19 196:8 197:22 198:12,14 199:2 204:9 205:9 205:15,20,23 207:23 208:8 209:8 211:19 212:10 214:10,23 215:16 217:17,18 218:21 224:8,13 225:1 226:12,25 236:12 pandemic 26:13 26:18,25 28:4 60:3 paper 90:10 paragraph 44:13 75:1 76:2 77:6 78:13,20,21 79:8 80:22,23 81:19 88:8 95:14,15,17 95:18,21,24 96:13 96:13 97:1,16,18 98:20 99:1 101:25 103:6,6,10,10 104:16,24 105:2 113:4,8 114:21,23 121:5 152:1 168:21 184:11,12 201:10,15,17 206:16,18 217:11 217:12 220:22 222:1 236:1	paragraphs 79:16 79:19 parameters 209:18 parkway 2:8 part 15:2,17 17:1 19:8 24:22 34:3 36:22 39:22 40:1 40:2 41:20 65:1 146:16 173:17 177:5 178:2 187:5 187:19 202:22 204:19,20 217:23 218:1 219:2,13,13 220:23 221:5,6,7,8 221:13,19,24,25 222:1,3,4,8,12,13 222:14 223:1,4,6 223:10,21 224:2 224:14,19 225:25 226:13 227:1,13 228:15 229:2 partial 142:9 participated 68:19 participating 11:17 68:18 particular 17:10 22:9 36:4,6,8 40:8 41:12,15 61:6 62:16 79:9 89:16 96:3,20 97:5,6,15 98:2 102:17,17 120:7 184:6 213:7 213:10,21 214:2 214:10,22 215:16 particularly 20:23 22:23 43:1 210:22 parties 11:25 12:18 29:23 33:24 parts 201:8 217:13 217:23
---	---	---	--

RESTRICTED CONFIDENTIAL

[party - pharma]

Page 29

party 132:25 194:13 204:6 205:19 216:12,15 216:16 222:2,12 222:20 224:13 225:25 227:6 228:15 229:9,15 229:18 230:18 231:21 232:23 233:2,13,15,18 234:3,25 236:2,6 236:11,14,20,23 236:24 237:2,13 237:18,21,24 238:4,14,21 239:5 239:7 242:10 patent 18:11 19:3 19:4,4,4,10 38:25 patents 18:25 19:7 patient 36:19 137:4 141:23 143:1 144:6,9,20 144:23 145:12 146:12 177:15 213:7 229:24,25 patient's 141:22 142:25 patients 118:11 139:13 149:1 165:11 166:9 169:8,17 172:7 190:16 213:2,3 218:3 227:17 patterns 37:25 pause 55:16 pay 105:15,18,24 105:25 106:7 192:13 193:2 212:10 223:17 224:20,22 225:12 225:12 229:4,4,15	229:25 230:8 237:24 239:6 payers 75:5 paying 223:19 229:20 236:7 payment 205:9 209:5,7 211:16 212:9,13 237:22 payments 214:15 217:16 225:5,11 225:17 226:8,14 226:17,17 227:7 227:11 228:14 229:9,11,16 payor 209:6,9 213:10,25 214:7 214:17 215:21 216:1,1,7,11 217:11,13 225:2 229:15 232:23 233:2,13,15,18 236:24,24 237:2 238:4,14,21 payor's 216:8,8 payors 105:6,15 105:17 106:7 111:9 131:6 132:25 194:13 195:2 204:7 205:19,19 214:17 216:4,13,15,16 219:7,16 220:1 222:2,12,20 224:13 225:25 227:6 228:15 229:9,19 230:18 231:21 234:3,25 236:2,6,12,15,18 236:20 237:9,12 237:13,19,24 239:5,7	pays 37:22 216:17 216:18,18 pbm 236:18,20 237:9,10,11,12 pbms 236:21 pc 4:18 5:2 penalty 11:24 pending 29:16,20 29:22 30:1 31:8 101:8 112:3 128:6 129:22 206:5 215:3 pennsylvania 1:13 2:4 3:7,20 5:14 6:4 people 37:8,11,12 39:16 48:6,8 50:4 62:24 63:1,3 86:23 122:21 145:6 152:23,25 161:20 162:2 165:19 183:17,17 194:1,16 195:6 197:1,21 198:1 199:11,16,21 200:11 211:6 218:6 222:22,23 223:22,24 perceived 164:3 164:13 232:16 percent 210:16 211:17 223:10 percentage 18:10 performed 85:6 period 17:22 35:15 43:9 45:16 78:6 100:9,20 128:25 131:8 133:3,5 171:21 194:2,16 228:5 239:23 240:6	perjury 11:24 permit 32:17 100:8 154:25 155:17,24 180:22 213:21 permitted 34:4 109:7 118:24,25 permitting 118:6 125:5 persist 99:20 109:17 129:14 person 11:22 28:24 61:1,15 62:4 137:16 161:22,22 perspective 97:25 101:23 110:12 121:21 124:8 125:24 130:6 131:13 138:7 145:20 152:18 156:13,23 161:12 169:23 185:22 190:3 199:7 200:10 204:5 persuasive 93:10 pertinent 194:8 pervasive 81:25 82:3,22,23 83:2 90:4,23 94:6 perverse 201:19 204:12 ph.d 244:2,24 245:2,4,12 ph.d. 1:11 2:5 8:8 10:2 40:24 41:5 56:19 185:6 242:6 243:5 ph.d.s 50:2 pharma 3:21
---	---	--	--

RESTRICTED CONFIDENTIAL

[pharmaceutical - practices]

Page 30

pharmaceutical 3:8,8,14,15 15:9 15:11 16:11,25 17:1,13 20:7,9 21:20 22:12,15,22 27:5,9 32:9,25 33:3 35:21 39:21 40:9,16 41:12,17 41:20 42:13 54:8 84:5 88:24 98:1 105:7,13 106:20 107:8,10 108:11 108:25 110:7 116:16 125:1 126:9 133:12 148:23 163:3 186:23 187:9 188:4 191:16,23 191:24 197:14 200:9 201:22 202:11,21 204:17 209:24 210:6,18 211:20 235:22 pharmaceuticals 4:6 6:6,11,15 22:4 42:3 168:23 pharmacies 105:13,24 106:8 108:13 118:11 119:1 125:2 210:21 211:1,8 237:14,24 239:6 pharmacist 169:11 173:1 174:11,18 pharmacists 174:4 176:13 177:22,25 179:2 pharmacy 6:25 33:2,2 108:9 118:12 124:12	190:10 204:9 225:3 229:4,20,23 229:23 230:1,3,6 236:15,16 237:22 238:22 239:8 phase 227:19 228:3 229:14 philadelphia 2:4 3:7 73:14 phone 100:11 153:20 154:17 155:8 phrase 62:12 75:14 76:15 77:5 113:9 120:23 127:15 143:12 172:18 phrases 232:12 physically 11:18 physician 157:18 157:20 physicians 118:12 174:4 176:12 177:22,25 179:2 192:17,23 pick 202:17 picked 185:9 picture 126:21 pietragallo 6:2 pietragallo.com 6:3 pills 175:24 pittsburgh 3:20 6:4 pizzi 6:7 place 210:13 242:7 places 74:25 plaintiff 87:12,14 87:19 plaintiff's 13:9 24:18,20,25 25:1	25:14 52:4,16 plaintiffs 2:10,14 2:19,25 8:6 24:4 25:20 26:2 28:1,9 29:2,7,8,13,17,23 30:4,14 31:4 33:12,25 34:16 35:9 44:6,13 56:17 59:16 64:13 64:18 72:22 76:3 87:17 147:8,17 180:18 181:1 206:19 plan 73:20 217:19 217:20 220:23 221:7,19,25 222:4 222:8 223:1,16 224:2 plans 217:24 218:11,11,12,13 221:1,22 222:12 222:13,21,24 223:10,12,21,23 224:14,20 225:6 225:25 227:2 228:15 plant 42:1,16,22 plaza 4:15 please 11:12 12:3 12:13 13:16 31:17 34:13 44:4 56:3 56:11 57:1 58:13 71:9 86:2 95:9 96:10 99:24 112:17 123:17 125:21 148:6 150:12 153:22 160:13,13 203:6 206:6 215:13 228:23 232:12,24 234:22 235:8	plenty 126:5,25 plus 113:18 116:19 132:13 pocket 185:9 202:17 224:22 229:25 point 135:22 141:13 154:1 169:5,7,8 189:9 190:6 198:9 205:3 207:23 208:22,25 217:6 224:25 225:19,22 229:19 229:21 230:1 235:7 pointing 111:16 points 169:2 policy 14:9,13 39:22 183:6 202:20 204:16,20 portion 30:25 posited 30:17 position 14:6 16:14 162:6 180:6 186:4 187:8,14 188:13 190:14 202:10,12,21 204:17 positive 140:7,14 140:20 possibilities 202:15 possibility 185:19 188:18 possible 193:17,23 potential 148:1 149:10 215:24 practices 21:12 88:17,19 89:1,4,14 89:17,18 90:19 105:14 106:17
---	--	---	--

RESTRICTED CONFIDENTIAL

[practices - production]

Page 31

113:17,18 preceding 103:6 precipitously 192:20 predicated 146:20 146:21 148:1 157:12,15 158:25 161:2 186:21 230:7 preliminary 72:24 73:18 premiums 223:18 223:19,21,24 224:8,20 229:4 prepare 69:1 83:16 prepared 83:17 preparing 73:10 prescribe 213:18 prescribed 158:8 158:10 213:4 prescribing 157:19,20 prescription 105:2 111:11 113:11 114:23 115:22 116:16,23 117:17 118:8,25 119:7 121:8 122:20 124:25 125:10 126:3 133:19 136:2 141:8,17,19 141:21 142:24 145:22 152:3 156:15 157:13,15 158:16,24 161:15 163:2 178:20 190:5,8 198:3 202:14 209:24 210:17,20 220:25 221:20 222:9	223:4 224:19,23 226:3,9 229:1,5,23 231:18 235:1 236:17 237:22 238:2 prescriptions 38:1 38:2 221:15 present 7:7 11:18 30:21 54:7 154:12 presentations 54:5 presently 31:12 president 39:12 press 8:11 167:6 pressure 134:8,18 134:24 135:4,6 154:5 174:7 175:4 191:2,8 192:1 193:25 200:8 presumable 214:16 presumes 164:6,8 presumption 180:2 pretty 48:1,9 62:15 216:2,4 prevent 110:20 134:21 135:21 137:12 192:2 prevention 136:3 136:17,22 137:11 previous 26:16 28:4 189:13 209:21 231:12 previously 30:18 158:13 161:10,24 166:12 220:4 price 15:12 126:21 126:24 127:1,6,16 127:16 130:1,10 130:21,24 131:18 181:11 182:3,7,19	182:21 183:1,7,9 183:12,21,24 186:21 187:23 188:19 189:3,18 204:9 207:22 208:8 225:1 priced 22:15 prices 22:17 39:3 226:20 pricing 16:1 17:13 22:14 23:14 36:13 37:5,18 38:19 primary 136:17 136:22 137:11 princeton 5:21 principals 27:21 princeton 3:8,14 175:11 print 121:22 prior 29:8,12 35:8 35:14 39:9 42:7 private 65:25,25 220:24 221:2,20 221:22 222:2,9,13 223:20 224:13 privilege 53:21 155:17 180:21 probable 163:8,10 probably 26:21 38:20 40:20 168:1 problem 13:21 212:22 215:4 233:7 proceed 12:13 94:21 101:4 111:25 process 15:15 45:24 69:19 73:24 121:20,23,24 produce 64:18 69:17 70:16	produced 45:7 64:10,12 65:1 66:4,12 70:10 86:22 88:4 108:20 116:18 117:18 118:2,14 119:11 120:18 121:8 190:10 producing 188:6 product 19:19,21 25:10 36:1 37:19 38:25 41:22,23 53:21 89:3 103:24 104:12,15 105:10 105:16,22,25 106:12 107:1,9,23 108:4,5 110:21 113:9,10,19 114:3 114:6 116:22 118:18,21 120:2 123:4,7 124:9,12 124:19,22 125:9 126:22 145:15,23 146:11,13,14,18 148:2,2,5 152:21 157:16 160:24 163:3 173:6 178:5 180:21 182:22 187:12,13 197:13 198:21 204:9 205:20,23 208:16 209:5,9 210:9,18 212:13 213:24 214:19 215:21 216:9 218:16 222:3 230:6,9 234:6,7 product's 120:3,3 147:25 production 9:6 24:10 64:14
---	---	--	---

RESTRICTED CONFIDENTIAL

[production - purity]

Page 32

123:10 products 1:3 16:25 18:4,11 19:16 21:24 22:8 22:10,12,15 23:14 23:15 24:10,11,19 24:23,23 25:4,12 25:16,22 31:19 35:18,21 36:16 37:7,9,20,21,22,24 37:25 38:8,10,11 38:19,24 39:4 40:9,17 41:19,25 41:25 42:1,4,8,13 42:14,16 62:14,17 64:7,23 65:7,10,21 65:22,23,24 66:12 76:4,12,13,16,17 77:6,8,13,19,23,24 78:3,10,15,23 81:5 82:1,6 84:11 85:25 86:4,6 88:23 89:12 91:6 91:16 93:19 96:12 96:25 97:8,12,21 98:14 101:22 102:5,6,11 104:18 105:5,7,9,14,18 106:7,8,18 107:11 108:10,11,17,19 110:8,14 113:12 113:15 115:7,7,24 116:5,11,17 117:9 117:15,23,24,25 118:7,12 121:15 124:10 125:2 126:8 130:8,13 131:6,11,14 132:13 138:9,12 138:18 139:7 144:8,22 146:3,4	148:8,9,24 149:4 149:11 151:12 152:4,9,21,24 156:4,6,12,17,19 156:21,22,23 157:22 159:1 160:17,23 161:13 162:3,4 163:4,16 164:7,9,21 165:1,4 165:4 166:1,15 169:24,25 170:7,8 170:12 171:5,6,19 172:5,8,10,13 173:10,12,17,18 174:6,12,12,20 175:5,8,11,11,23 176:7,7,14,15,18 176:19,24 177:2,6 177:13,23 178:1,2 178:5,20 179:3,21 182:11,12,15,16 183:3,6,18,19 184:19,24 185:4,7 185:17,18,21 186:1,2,6 187:1,15 188:6,7,9 189:16 190:1,3 191:2,16 191:17,22,24 192:19 193:19 194:15,24 197:12 197:20,20,24 198:2 199:9,22 200:13 201:19 202:17,19 204:5 204:18,21 205:16 208:17 210:7,18 210:22 211:3,9 212:10 213:24 226:11 227:9,15 227:21 231:19 240:2 241:2,4	professional 14:4 professor 14:8 26:7 professors 23:25 23:25 program 217:22 218:7,8,10 programs 217:22 218:4,5,6 progressing 135:22 project 61:7,19 62:5 63:5 projections 210:13 promotion 36:13 proof 118:4,4 properly 198:21 property 19:5,6 prospective 226:7 prospectively 130:7 protect 80:5 128:13 184:17 protected 53:20 protecting 109:22 184:14 prove 117:21 provide 13:6 17:5 21:6,10 30:12,23 32:22 44:14,21 50:25 51:18,23 52:3,16 54:2 64:18 73:17 75:2 89:5,9 92:10,17 99:5 103:7 111:7 137:4 141:23 143:1,10 209:17 223:10 228:22 236:21 provided 32:6 54:1 56:7 59:7	64:13 97:16 98:16 138:12,18 144:9 144:23 148:12 155:4 164:14 221:2,22 provides 85:8 146:18 169:11 providing 44:18 75:18,18,21 97:1 170:15 province 55:1 public 14:9 171:6 184:17 223:20 242:4 245:19 publications 54:5 published 23:14 85:10 126:6 publishes 173:16 puerto 42:23 pull 43:10,15 52:22 56:10 57:22 58:13 74:13 punish 203:18 punishment 203:11 punitive 200:16 purchase 197:23 199:25 200:1 205:10 209:12,14 209:15,19 224:18 227:9 purchased 132:19 132:24 133:1 197:22 199:21 210:3 211:18,18 213:2,4 purchases 226:3 purchasing 185:18 purity 121:11 122:1,4
--	--	--	---

RESTRICTED CONFIDENTIAL

[purpose - receive]

Page 33

purpose 67:11 154:4,8 purposes 114:14 138:14 143:21 149:2 purview 210:25 put 45:20 48:13,24 71:21 74:13 90:14 95:5 105:23 119:17 154:6 157:3 161:8,21 173:24 184:9 202:6 203:1 putting 45:24 120:7	101:8,11 106:6 109:2,2,6,6,12,20 109:24 110:1 112:3,6 116:11 120:9 123:17 124:4,5 126:14,14 127:22,24 128:6 128:19,21,24 129:3,3,15,18,23 132:21 138:6 141:18 142:8,23 143:7 144:10,11 144:14,18 146:25 147:13 150:6,8 151:10 159:14,15 160:11,14,21 161:18,19 162:1 163:19,24 166:6 169:4,6 179:6,10 179:12 181:15 187:19 196:18 197:10 201:8,12 203:6 205:13 206:5 213:16,16 215:2,13 219:11 222:6,11 228:11 228:12 230:22 231:7,9,11,12 232:11 233:22 235:5 236:3,10 237:1 238:10 239:3,12 240:17 questioning 174:2 questions 9:12 12:19 13:5 20:22 34:5 74:24 80:14 92:4,6 100:18,19 100:22 101:2 169:13 questrom 14:11	queue 95:9 quite 19:2 85:2 109:21 182:12 183:14 201:7 203:6,17 222:5 r r 2:1,12 3:1 4:1 5:1 6:1 7:1 11:15 242:1 244:3,3 rachel 2:16 radam's 184:20 185:4 raised 129:1 ranbaxy 41:25 42:15 raspanti 6:2 rate 49:15,20 60:11,13,16,19 rationale 184:13 reach 81:1 84:18 84:21 reached 75:25 reaching 65:4,4 83:20 84:1 86:11 87:6 238:21 read 10:8 39:17 44:4 52:9 54:19 54:21 87:11,18,21 87:24,24 88:5 99:24 101:8,14 110:1 144:13,16 144:18,18 153:20 153:22 155:13 169:12,14 173:15 201:23 219:14 243:9 245:5 reading 154:15,16 154:20,21 reaffirms 170:6 real 112:8	reality 100:17 realized 160:17 really 17:22 54:17 71:1,10,11 73:15 110:10 122:7 158:10 198:18 211:3 226:18 227:16 229:11 232:11 236:25 239:11 reason 30:17 33:15 55:19 59:8 98:20 102:17 115:18 218:21 243:11 244:6,9,12 244:15,18,21 reasons 95:25 96:3 96:20 97:7,19 98:11 99:2 103:7 103:10 reassess 235:12 rebazan 3:11 rebecca 3:11 recall 28:8 29:10 167:22 168:18 173:17 174:15,16 178:3 recalled 65:14,18 65:21 76:6,7 77:19 175:6,8,19 176:24 177:3 178:1,9,10 192:19 194:15 199:13,23 recalls 8:13 165:11 166:10 167:8 170:25 171:8 175:10 182:13 receipt 243:18 receive 53:10 155:7 223:21,23
---	---	---	---

RESTRICTED CONFIDENTIAL

[receive - report]

Page 34

224:3 225:11,13 226:1 227:7 229:9 230:2,3,13 233:2 233:18 234:4,6 received 145:13 159:24,24 160:5 160:22,23 164:14 180:17 232:4,16 receiving 232:23 receptor 8:12 167:7 recess 112:24 recognize 53:7 56:13 59:2 recognized 105:4 recommends 178:3 record 11:2,11 12:23 57:5,12,14 57:17 74:1,11 76:22,24 77:1,3 80:6 91:21,23,25 92:2 94:16,18,20 94:22,23 95:5,7,12 100:14,17 109:22 112:23 113:2 128:13,16 150:12 150:14,17 155:14 180:11,15 206:9 206:13 235:15,19 241:12,14 recorded 11:3 redrafting 46:17 reduces 221:17 reducing 202:16 refer 77:18 95:15 188:14 reference 79:7 181:20 referenced 243:6	references 93:9 referred 83:7 94:7 186:11 referring 46:25 75:6 77:12 82:9 83:3 91:7,17 95:24 120:21,25 122:17 166:3 168:17 173:10 175:22 181:21 222:2,11,19 235:23 238:18 239:10 refers 88:15 refund 25:10 207:22 refused 100:14 regarding 11:4 75:3 111:7 172:5 regardless 154:3 191:2 232:3,15 regular 211:7 regulated 114:3 124:22 190:1 regulation 14:16 15:9 16:1 17:14 21:19,23 22:1,4,8 22:10,11 23:15 24:10 32:10,24 84:4 85:4,24 86:3 98:1 125:11 186:22,23 197:14 regulations 105:11 121:6 122:17 125:8 184:17 regulator 117:4,15 117:21 119:7 124:15 125:24 regulator's 110:12 125:24 161:12 190:3	regulatory 23:1 46:13 reimbursed 15:12 223:6 236:7 reimbursement 17:14 37:6,22 223:11 relabeled 65:25 relabelers 66:7 relate 54:7 114:17 related 14:15 17:8 17:13 19:9 20:12 21:14,23,25 22:8 24:9 32:23 44:15 44:17 45:18 62:14 62:17 64:24 91:16 92:21 93:9,18,24 122:13 123:2,23 127:1 145:23 146:2 151:9 152:20 156:18 158:24 191:9 193:25 195:10 209:7 242:10 relates 1:4 44:22 relating 39:25 relation 18:13 45:11 relationship 29:12 127:3 236:19 237:11 relatively 134:12 released 39:13 relevant 46:14 128:25 131:7 210:22 223:7 relied 83:16,20 84:1,13,18,21 85:12,15,18,20,23 91:10 94:6 209:2 209:11 210:2	rely 65:3 relying 188:16 189:8,11 209:2,4,6 remains 147:14 remedies 185:8 remember 28:6 106:5 177:3 remind 75:10 reminds 172:24 177:24 remotely 11:20 rena 1:11 2:5 8:8 10:2 11:4 12:8,24 56:19 242:6 243:5 244:2,24 245:2,4 245:12 render 32:5 repackaged 65:24 repackager 65:13 65:17 repackagers 66:7 repair 225:12 repeat 46:3 123:16 191:19 203:7 219:12 rephrase 13:16 159:21 replacement 169:11 173:2 174:18 175:16 report 15:25 16:1 39:13,17 45:7,22 45:25 46:18,21,24 47:12,21 50:17,19 50:22 51:2,4,11,17 51:20 52:1,5,17,20 57:25 58:5 64:22 65:2,4,8 66:13 74:14,21,24 77:16 79:8,16,18 81:20 82:19 83:14 86:9
---	---	--	---

RESTRICTED CONFIDENTIAL

[report - reviewed]

Page 35

86:23 88:7 95:15 96:14 97:16 99:2 102:8 104:21,25 104:25 106:14 111:22 113:5 114:15 116:2 121:3,5 126:9 135:1 138:8 143:21 145:10 148:17 149:2 151:2,19,25 152:19 153:11 164:23,24 167:10 167:17,19 169:24 170:9,11 178:18 181:20,22 184:10 184:12 193:15 201:10 203:4 206:3,15 212:1,5 217:5,10 235:21 reporter 1:15,16 10:7 11:8,11,16 12:5,12 14:23 16:15 20:8,11 28:17,20 33:1,5 35:19 36:14 38:3 42:17,20 44:9 46:2 49:9 52:8 58:3 61:9 65:15 66:18 67:4 69:25 76:19 79:17,21 88:11 89:7 90:2,6 90:14 92:14 94:1 101:7,13 102:25 103:3 105:17 107:17,20 109:23 115:3,9 117:6 118:19 123:16 132:16 133:17 136:19,21,25 137:1 139:21	140:1,4 142:6,11 146:21 150:3,9,11 151:14 152:12 153:22 154:14 166:23 170:3 171:23 184:22 191:18 192:3 195:1 204:25 205:4,21 207:14 208:2,10 209:14 211:11 212:8,16 212:18,20 219:1,9 225:20 228:7 230:21 235:6 242:4 reporting 11:19 12:2 reports 54:4 86:22 87:1 88:4 92:21 137:23 represent 12:18 29:13,16 30:4 31:4 59:5 representation 59:9 69:14 representative 87:22 representatives 147:9,17 represented 25:3 27:5,14 121:12 representing 29:23 represents 156:13 request 9:1,6 54:20 55:3,24 56:6 59:7 70:18 requested 52:10 56:4 101:15 110:2 requests 53:13,17 53:23	require 30:21 135:9,16 240:6 required 88:24 89:5,9 223:3 224:18,22 245:13 requirement 30:9 31:12 requirements 84:7 119:13,17 121:10 requires 117:15 requiring 135:23 research 14:13 16:10 32:21 35:10 35:14 36:12 38:15 40:8,15 41:11,14 41:16 50:5 209:23 212:2 researched 36:3 37:23 researching 36:10 38:18 respect 97:7,20 103:13 133:12 216:24 respectfully 33:16 54:24 respective 226:1 respond 53:16 54:22 55:24 102:9 110:5,24 145:1 responded 129:16 129:17 responding 96:9 109:21 response 55:2,6,12 59:7 86:20 99:23 101:9,10,17 103:1 189:13 responses 8:7 56:18 99:22 101:2 101:5	responsive 54:16 54:25 55:13 restate 40:10 215:12 232:13 restricted 1:8 result 137:16 238:5,15 242:11 resulted 153:7 resume 53:24 112:18 retail 211:7 229:20 retailers 66:1 206:24 207:13,17 208:1,5,9,13,15,19 208:22 retained 27:19 35:8 44:14,21 75:2 111:6 retention 8:3 27:18 34:22 35:8 43:13 44:5,7 49:14 retrospective 226:14,17 retrospectively 226:8 227:14 return 243:13,17 reveal 20:22 30:10 30:19,20 32:1 33:20 53:19 revealed 34:13 101:2 reveals 31:15 revenue 15:12 reverse 26:20 review 65:13,16 69:11 86:10 87:5 90:17 243:7 reviewed 46:1,13 87:8 91:15 93:7
--	---	---	--

RESTRICTED CONFIDENTIAL

[reviewed - see]

Page 36

133:21 147:6,7 rgeman 2:17 rico 42:23 right 16:22 17:23 23:13 25:11,12,18 25:18 40:18 41:2 41:4,6 49:8,16 59:17 60:1 61:22 62:23 63:21,22 67:4,16 68:8,20,24 75:19 85:20 98:12 106:8 114:2 116:6 127:7,17,18 132:25 133:25 134:19 136:7 147:20 149:19 150:22 157:5,25 160:8 164:15 167:17,21 168:12 168:20 170:16 171:2 172:16,19 173:12,25 174:22 175:25 177:6,16 178:10 181:25 184:10 192:13 193:12 195:18 196:3 197:8 200:2 204:3 208:6 209:4 213:2,7 214:21 218:18 227:2 236:10,24 risk 89:2 135:5 161:7,12,21 163:1 163:7,9 rite 5:10 road 5:20 rockett 6:17 rockett.shevon 6:18 room 11:19	rooney 4:18 5:2 rose 4:8 roseland 2:9 ross 4:11 roszel 5:20 round 215:10,10 route 116:22 ruben 2:3,3 28:12 129:5 149:25 243:1,2 rude 162:14 ruler 2:13 rules 109:11 114:8 125:3,4 runs 229:24 s s 2:1,21 3:1 4:1 5:1 6:1 7:1 8:1 11:15 244:3 sadly 14:19 26:20 133:9 safe 113:18 114:7 114:11 115:11,25 116:19 117:18 118:2,15 123:10 125:6 safety 36:22 37:1 37:7,13 113:13,24 114:5,10,16 121:10 152:2 190:13 201:18 sagoldberg 3:3 sale 62:14,17 106:9,21 146:5 148:3,7,11,24 152:6,22 154:1,12 207:23 208:19,20 225:1,19,22 227:8 229:19,21 230:1 238:5	sales 64:22 65:10 66:11 209:4,24 210:7,17 213:24 217:15 222:21 sanctioned 100:10 sanger 2:11 sara's 50:1 sarah 48:7 50:3,5 50:15 53:25 62:20 62:21,21,22,23,23 63:2,3 satisfy 55:14 238:5 238:15 saved 144:6,20 saving 145:6 saw 171:14 saying 23:10 57:4 71:15,23,24 85:22 93:3,17 120:10 122:8 136:9 172:16 174:19 175:22,25 176:20 180:1,4 190:23 215:7 230:8 says 44:12 49:15 60:8 61:4 63:6,13 63:24 65:13,16 66:17 78:14,20 81:23 83:15 85:18 99:2 120:2 121:22 153:21 168:6,15 168:15 170:19 172:24 174:16 176:9 186:15 201:24 222:7 scenario 182:4 schedule 224:21 school 14:10,11,14 14:15 189:3 sciegen 6:15	science's 15:25 scope 45:1,11 102:8 106:14 107:6 108:7 110:23 111:2,3,22 111:25 121:3 134:10 135:1 137:6 138:4,20 139:4,17 140:10 141:25 143:3 144:25 145:18 147:22 148:17 150:24 151:19 156:9 157:7 158:2 158:22 160:3 161:10 163:12 165:14,23 169:21 170:18 171:17 172:21 174:24 176:3 190:22 192:9 193:15 200:18 203:3,15 234:14 238:8 screen 43:21 56:14 63:10,17 67:10 72:11 83:14 scripts 4:17 scroll 114:20 second 22:20 44:4 54:15 74:22 76:22 90:7 91:9,19 95:20,23 113:6 150:12 168:20 185:19 217:7 221:8,9 seconds 150:4 230:6 see 43:20 44:24 48:15,17,20 59:11 59:12,14 63:11 66:17,23 67:17
--	---	--	---

RESTRICTED CONFIDENTIAL

[see - sorry]

Page 37

68:3,12,23 69:7,9 72:13,17 73:19 76:9 85:13 88:5 90:7 91:13 96:1 103:16 109:19 124:16 128:14 167:8,25 168:15 168:18,19,25 169:3,14 206:25 218:14 241:9 seeing 56:23 seek 191:9 seeks 127:19 seen 50:9 57:4,19 86:24 226:10 segments 34:7 selected 86:7 sell 89:12 105:14 107:9 108:15 110:8 116:17 123:7 124:12 126:10 163:4 selling 110:20 188:7 194:23 208:17 sells 125:2 222:24 seminar 54:4 senior's 227:8 seniors 223:3,23 224:8,18 229:1 sense 21:15 48:12 48:23 115:5 sent 154:23 180:25 243:14 sentence 113:8 114:22 173:11,23 221:3,6,9,13 222:7 separate 35:16 56:4 71:17 146:1 148:13 217:16 224:7	september 72:15 sequella 192:2 served 21:5 service 218:10 services 17:5 44:16,17 236:21 237:13 serving 20:13 21:4 set 53:16 84:22 237:2 242:13 seth 3:3 12:17 33:16 46:23 54:24 66:18 67:22 88:11 95:3 109:16 142:19 143:5 167:9 188:25 215:1 219:13 230:24 233:8 235:6 sets 217:14 setting 211:5 226:19,19 237:23 239:13 settled 25:12 share 26:23,23 51:17 63:13,25 64:4,10 65:3 shared 51:7 sharpen 55:7 sheet 243:11 shevon 6:17 short 57:15 64:21 74:8 150:15 180:12 206:10 235:16 shorthand 242:3,8 show 18:21 43:12 126:20 showing 138:25 shows 181:23	shuffling 90:10 sic 93:10 sick 71:4,16,25 73:15 211:6 side 24:8,14,20,20 24:25,25 25:2,14 225:5,11,17 229:9 229:15 sided 63:8 sign 10:8 243:12 signature 242:16 signed 243:20 significant 42:12 88:25 similar 32:5 similarly 38:22 simply 69:17 80:7 128:23 200:10 single 21:17 27:7 73:15 80:6 215:24 sir 108:2 140:12 140:18,25 149:24 158:6 159:7 160:9 163:24 167:25 170:20 178:25 181:15 193:15 195:19,24 196:6 205:13 209:21 220:12,20 221:12 223:8 228:11 231:7 sit 26:21 sitting 177:7 six 127:24 215:5 sketch 15:6 skipped 221:4,14 slack 2:11 slater 2:7,7 slaterdavis.com 2:12	slow 201:7 slowly 153:23 smolij 3:5 solco 3:8,15 sold 66:5 76:5 105:5 108:12,21 113:14,19 115:21 117:9,16 118:7,10 118:22,25 119:8 119:16 120:16 121:14 122:20 125:12 126:1 145:24 146:8 149:6 152:5 154:3 190:8,10 195:18 195:20 196:3,11 198:20 208:15 210:25 223:2,23 237:22 solely 77:21 solutions 243:23 somebody 135:8 135:15 175:24 177:3,4,11 208:23 someone's 137:16 170:9 soothing 185:5 sorry 14:23 16:18 24:21 25:7 28:17 28:21 29:19,25 30:22 33:10 38:3 38:5 40:10 42:20 44:9 46:2 47:8 49:9 52:6 58:12 58:14,18 61:24 62:3 63:16 64:11 65:15 66:18 72:9 72:9 76:19 77:15 78:17,17 79:2 80:15,15 81:20 88:9,13 89:8
---	---	--	--

RESTRICTED CONFIDENTIAL

[sorry - stroke]

Page 38

102:25 118:19 125:21 132:16 136:21 142:5,6 146:25 149:25 152:13,17 158:16 160:9 167:19,25 170:3 171:23 178:25 181:15 184:22 185:1 191:18 201:6 203:5,16 205:1 212:20 218:11,17 219:9 222:6 225:20 230:21,23 232:10 234:20 237:1 238:10,18 239:3 sort 37:12 50:12 162:16 sound 49:16 sounded 144:15 sounds 49:7 74:5 sources 210:12 sourcing 236:6 south 3:6 5:8 speak 75:10 176:1 speaking 142:3,7 142:14 special 22:2 specialty 22:19 211:1 226:18 specific 22:23 41:7 50:6 51:1,24 67:24 73:12 84:15 84:21 88:18 91:14 93:18 97:19 98:5 98:25 101:24 103:19 114:4 118:16 143:17 149:4 166:3,16 176:9 177:23	178:22 209:17 210:22 212:11 213:1 215:21 216:1,2,4,6 specifically 22:21 39:14 64:8 85:12 86:8,8 92:21 93:7 134:6 165:15 172:11 175:3 212:12 specifications 240:5,19 specificity 216:14 216:24 specifics 56:1 99:4 99:6 spend 228:1 spent 35:25 71:16 73:8 84:6,9 sphere 20:23 spoke 165:20 171:11 sponsors 220:24 221:19 222:8 224:3 st 4:16 staff 46:10 47:25 48:4,5,10 69:9 83:17 209:12 standard 1:14 15:21 16:5,5,7 23:9,10,11,19 110:15 113:12,16 113:20 115:8 118:13 119:11,20 119:22,24 120:13 120:18,24 121:14 124:14,24 125:5 126:2,4,7,11 131:11 146:4,7,13 148:11 149:6	152:22 156:20 159:3 161:14 163:5 164:10 165:2,6 188:8 190:4 209:23 210:5 standards 105:15 110:9 111:18 117:1 120:19,20 120:25 122:24 123:9 187:12 190:13 standpoint 36:21 125:7 149:15,17 149:22 stanoch 2:22 59:13 start 32:12 66:15 66:19 74:20,23,25 130:6 152:16 182:13 started 28:4 46:21 59:24 60:2 142:14 174:2 starting 29:9 48:1 162:18 starts 235:24 state 6:14 12:3,22 152:1 209:5,9 214:8,18 215:22 217:18 218:4,5,10 218:16,22 stated 99:1 158:13 166:12 171:3 220:4 statement 123:1 123:23 144:15 167:24 173:15,21 178:17,22 179:15 180:1 185:15 190:7 208:25	statements 180:4 233:24 states 1:1 39:17 64:25 103:10,10 105:4,12 107:11 124:23 161:16 175:3 187:9 201:22 207:6,16 236:18 status 113:9,10 statute 124:10 steno 241:12 stenographic 11:11 94:22 stereotype 242:4 stent 198:4 stents 136:1 steven 3:18 steven.hunchuck 3:19 stipulations 9:9 stock 106:8 stone 48:7 53:25 62:22,23,23 stop 96:10 101:4 109:18 129:5,5,6,9 129:16 163:5 stopping 162:17 stoy 6:3 strategy 14:21,25 street 2:4,17,24 3:6,13 4:20 5:4,8 6:9,14,18 7:4 strength 121:11 122:4 stricken 150:10 strike 75:25 94:14 133:21 145:12 147:6 150:7 stroke 135:5,15 137:17
---	--	---	---

RESTRICTED CONFIDENTIAL

[strokes - term]

Page 39

strokes 134:24 135:22,24 136:16 136:18,23 137:12 student 189:3 studied 42:7 172:4 studies 15:20 23:23 54:4 138:25 studying 36:10 stuff 23:11,23 24:3 subject 18:5,25 19:13 21:11 submit 69:19 73:21,22 submitted 59:13 70:14 72:4 subscribed 245:14 subsidies 225:6 226:1 suffer 191:7 suffered 204:7 225:15 suggest 226:10 227:6 229:13 suggested 191:12 suggesting 202:7 suite 2:4,13 3:13 4:5,11,15,20 5:4 6:24 7:4 summarized 50:24 summer 48:1,2,3 71:25 supplied 190:18 suppliers 166:15 supply 88:23 106:20 115:6,22 118:1 122:21 123:2,3,20,24,25 124:3,8,19,25 125:9,10,17 126:8 126:15,23,24 127:2 130:9,11,19	130:20,23 131:16 131:17,20 132:2,6 132:7,20 145:25 146:17 156:18 159:1 161:2,4 162:4 164:9,25 165:7 170:6,11 181:10,12,18,23 182:5,8,17,18,19 182:22 183:2,5,18 186:20,25 187:22 188:15,17 189:4 189:10,16,17,17 189:23 196:3 197:17 201:22 230:14 231:3,14 231:17 232:1 235:22 236:17 support 17:6 23:2 63:1 71:3 126:14 136:3 supporting 82:15 180:5 supportive 90:25 sure 12:24 14:7 15:7 21:17 26:12 32:12 37:17 40:12 46:4 49:18,21 52:8 63:18 67:25 68:2 69:2 73:20 95:8 101:13 106:6 112:8,11 120:8 184:9 185:1 189:24 191:6,20 193:8 214:4 217:7 surmise 21:21 sustained 23:2 swann 185:6 swear 11:12 12:6 switched 198:2	switching 176:16 sworn 12:9 245:14 systematic 82:5,8 90:1,3,23 93:9 t t 3:12 5:13 8:1 140:2 242:1,1 244:3,3 tab 43:10,23 44:1 52:22,23 57:23,24 58:8 166:18,21 table 10:1 take 13:20 18:23 43:14 45:19 47:10 67:5 74:1 121:17 139:14 164:2,12 170:21 177:15 180:7 190:19 192:6,12,25 193:10 206:6 235:7,11 taken 1:11 13:23 57:15 74:8 112:24 150:15 158:19 159:21 180:12 189:6 190:17 193:18 194:1 199:1 206:10 235:16 242:6 takes 69:5 talk 13:7 14:3 25:18,23 27:17 62:3 162:21 174:10,10,21 175:13 176:14 177:16 178:5 187:5,23 208:14 235:21 talked 151:6 156:2 172:18 181:9 183:14 230:11	talking 23:6,10 38:9 63:18,21 75:14 143:16 151:7 172:23 173:18,22 177:6 182:9 198:8,9 216:12,12,13,14 217:24,25 226:21 227:20 talks 78:13 126:6 taught 15:2,16 189:3 taxpayers 24:15 teach 14:25 16:11 23:16,17 teaching 14:17,21 14:24 23:11,22 32:20 71:2,19 72:1,2 team 51:18 54:8 tech 67:13,14,24 168:2 techniques 193:5 193:6 technological 14:16 technology 14:13 tell 26:1 33:18 51:14 56:5 129:12 telling 93:16 166:8 174:9 tells 228:21 tenure 23:18 term 97:25 98:5 103:22 114:1 121:18,25 122:7 122:11,12 123:8 144:3 145:9 149:3 151:23 153:10 158:6 182:5 186:10
--	---	---	--

RESTRICTED CONFIDENTIAL

[terms - time]

Page 40

terms 16:13 21:9 24:3 27:3 34:7 50:15,17 111:12 113:24 114:1 117:1 122:8,14,16 124:2,3 188:1 207:12,12,19 209:1 236:6 testified 12:9 147:18 testify 79:23 127:21 testifying 79:24 215:8 testimony 11:23 13:24 44:22 45:1 86:11 96:24 100:15 107:22 108:2,19 116:9 140:7,12,18 147:8 147:20 171:14 181:11 182:3,20 197:7 220:18,20 237:8 243:9,18 245:8 teva 4:6 6:11 78:1 175:10 texas 2:13 4:11 text 155:8 169:14 175:3 180:18 185:14,14 textbook 15:13,16 textbooks 15:22 16:3 126:25 texted 155:12,18 155:22 thank 12:14 13:19 21:1,2 30:11,21 32:19 33:5,6 34:20 45:15 47:7 52:11 53:22 55:21	68:1,3 79:21 80:9 93:22 95:19 96:11 103:3 108:8 110:6 112:13,20 115:4 125:22 135:2 136:25 140:4,4 143:5 145:2,4 152:15 167:11 175:1 176:5 179:19 187:18 189:1 192:3 196:17 205:4,5 208:10 212:20 219:21 228:24 239:21 theories 46:7 206:20,22 207:4 207:10 theory 156:13 182:7 183:1 186:19 187:21 188:15,17 189:8 189:11,22,23 197:24 206:22 therapeutic 134:2 137:21 138:1,13 138:18 143:10 146:2,5,9,10,17 147:18,24 149:18 150:20 151:7,11 153:2 156:3,7 158:18 159:6,20 159:25 160:6,16 164:14 170:15 171:15 183:12,13 183:15,24 184:3 185:25 186:13 194:3 199:17 230:12 233:12 234:4	therapeutically 185:13 therapy 198:4 thereof 242:12 thing 23:5 28:23 196:6 things 39:23 73:11 80:9 85:9 117:2,5 128:23 161:7 192:18 197:1 198:5 200:9 221:3 think 14:1 17:23 21:18 25:11 26:13 27:8 28:3,12 31:2 33:24 34:18 37:3 37:3,3 39:4 40:19 41:2 43:13 46:20 49:19 50:11,18 51:9,12 57:1 60:1 60:20,21 62:16 63:17 65:20 67:22 70:5 73:17 84:3 90:10 91:10 111:19 112:2 125:10 129:16,17 132:11 137:10 138:5 141:6,7 147:12 150:1 151:20,21 153:19 160:3 166:6 169:13 188:24 190:24,24 194:20 208:4 209:20 215:5,9 223:14 225:9 227:22,25 228:4 231:6 233:7 233:7,11 234:15 236:9 237:18 239:10 thinking 35:25 37:11,18,21 39:4	84:6,10,10 124:2,3 181:17 184:6 thinks 55:2 third 63:7 88:15 132:25 204:6 205:19 216:12,15 216:16 222:2,12 222:20 224:13 225:25 227:6 228:15 229:9,15 229:18 230:18 232:23 233:2,13 233:15,18 234:3 234:25 236:2,6,11 236:14,20,23,24 237:2,13,18,21,24 238:4,14,21 239:5 239:7 thornburg 5:7 thought 36:2,2 86:8 101:18,20 159:8 186:8 213:12,12 threat 41:19 three 6:9 17:23 18:1,3 25:12,16,19 25:19 60:17 71:17 80:8 168:3,4,4,10 175:9 217:13 thumbnail 15:6 thursday 1:12 tiffany 4:3 time 1:14 12:3 13:10,10,21 17:22 22:5,17 23:1,3 28:9 35:15,25 36:25 37:2 39:3 41:21 43:9,14 45:16 47:18 48:12 49:10,20,22 50:10 54:19 56:23 57:10
---	--	--	---

RESTRICTED CONFIDENTIAL

[time - u.s.]

Page 41

57:13,16 60:10,21 62:6 64:24 67:6 68:15 69:6,8,9,18 69:21 70:7,11,12 70:22 71:4,11,13 71:15,20,21,25 72:1,4,5,8,21,25 73:3,8 74:6,9 76:23 77:2 78:6 84:6,9 89:13 91:22 92:1 94:17 95:3,11 108:16 110:10 111:20 112:8,10,15,21,25 131:8 133:3,5 150:13,16 171:7 171:21 180:9,13 194:2,16 195:5,16 196:21,22,22 202:11 206:8,11 212:18 228:5 235:10,13,17 239:23 240:5 241:13 242:6 243:19 timeframe 38:14 39:10 243:8 times 94:12 109:20 127:24 128:20 153:12 160:4 179:13 196:19 200:4 215:5 titled 181:24 today 12:20 13:24 25:9 30:10 92:11 180:18 183:14 234:21 told 173:24,24 220:8,14,15	tolerance 161:12 163:1 tolerances 161:7 161:21 top 168:14 topic 40:25 torrent 78:2 93:25 total 69:12,22 210:16 217:15 221:17 toxins 39:14 tpp 232:4,6,15,18 tps 205:18 216:24,25 217:2 223:9 227:1 229:8 229:21 231:4,15 trade 5:4 105:12 105:13 106:19 113:14 116:24 119:8,19,21 120:13,15 138:11 139:10 156:21 161:15 162:5 163:2 183:17 190:9 197:4,8,16 197:21 202:14 210:19 211:7,10 211:12 217:25 235:3 trades 186:4 tragically 135:24 trailed 230:23 train 101:18,19 trained 50:4 transactions 230:5 transcript 30:25 243:6,20 245:5,8 transcription 242:7 traurig 4:2	traveling 71:17 treat 35:22 38:12 133:24 134:3,5 170:8 174:7 175:4 190:20 191:24 199:18 211:5 treated 135:6 233:3,20 treating 137:15 139:2,15 treatise 124:17 125:15 treatises 188:16 treatment 136:3 136:17,23 137:11 138:1,2 144:7,21 145:14 169:12 172:10 173:2 174:11,19 175:14 175:16 191:1,9,10 192:16 193:12 225:13 226:20 232:5,17 treatments 134:21 135:19,21 172:2 191:13 192:7 200:7 trials 133:11,14,15 tricare 218:7 tried 100:13,14 220:16 triple 73:23 true 103:13 117:7 136:15 205:18 242:7 245:8 try 13:7 33:17 102:3 162:22 trying 16:5 21:14 41:7 51:15 55:25 60:15 125:14 128:18,23 162:18	164:24 188:12 203:10,18 221:11 231:11 turn 64:15 68:22 90:7 95:14 104:24 166:18 167:23 184:16 201:10 206:15 turned 75:12 two 18:8 22:13 35:16 37:8 66:21 68:6,6 69:24 70:2 71:6 111:12,23 136:1 145:21 169:2,13 180:8 185:22,23 186:12 206:22 217:16 twofold 185:17 tylenol 13:25 type 23:23 32:1 160:21 202:20 212:4 213:25 214:7 216:8 226:16 227:11 types 17:16 19:16 22:23 35:17,20 38:25 39:1,3,15 43:5 51:24 185:23 185:23 209:6 226:9 229:10 239:4
u			
u.s. 3:9,9,15,15 66:5 86:4 88:24 89:10,12 97:14 98:3,6,16 106:18 106:21 108:10,11 108:15,21 110:8 110:12,16,21 113:14,19,22 114:8 115:22			

RESTRICTED CONFIDENTIAL

[u.s. - valsartan]

Page 42

116:17,24 117:14 117:16 119:8,19 119:21 120:12,14 120:17 121:14,21 122:13 124:14,23 125:12,23,24 126:1,11 132:14 132:20 135:20 136:20,24 138:11 139:9 145:24 146:5 148:7,10,25 149:7 156:21 161:11 162:5,6 163:4 164:10 165:2 174:8 182:17 183:6 186:4,5,6 187:2 188:6,7 190:2,2,9 190:14 194:24 197:14,16,21 202:10,20 204:16 204:20,23 209:25 210:19 211:1,20 215:23 235:3 237:9 uh 20:11 41:8 201:16 217:9 ulmer 7:2 ulmer.com 7:3 ultimately 42:15 125:2 199:23 unable 228:21 unadulterated 191:14 198:20 uncontaminated 191:14 undergo 38:25 underlying 137:11 191:25 235:4 underscores 185:15	understand 13:4 13:13,14,15,19 19:2 34:3 39:23 44:25 45:10 51:16 53:12,14 59:21 79:2 80:1,11 85:2 86:14,21 87:15 93:2 98:10 106:6 121:18,25 122:19 125:14 127:11 129:18 131:8 133:23 134:13,18 134:20 135:3 143:13 144:3 151:5,5 153:17 181:14 191:11 203:6,17 214:4 218:21 219:5 222:5 229:18,21 232:22 233:16 234:17,24 236:25 238:9 239:1,2,12 understanding 40:2,3 59:18 79:6 82:4,13 87:2 88:2 88:18 98:4 101:3 106:11,25 107:8 110:19 114:10 115:20 125:11 134:16 141:14 158:15 165:24 172:6 173:4,7 186:22 191:11,21 214:6 216:25 237:25 239:22 240:25 understood 13:18 underwent 198:4 underwrite 227:8 unit 11:3 74:7 112:22 113:1	180:10,14 206:12 235:14,18 united 1:1 39:17 105:4,12 107:11 124:23 161:16 187:9 201:22 223:2 236:18 universities 23:12 university 14:6,10 15:18,18,19 23:24 52:19 unjust 206:23 207:2,20 208:12 untreated 134:7 134:19,23 137:3 update 175:7 updated 54:1 updates 8:11 167:6 use 16:3 36:19 37:23,24,25 38:19 46:24 54:7,8 75:14 76:15 103:22 113:9,24 122:11,12 123:11 124:15 133:24 134:4 165:19 166:9 171:10 172:9,17,17 174:11 182:4 213:6,9 usefulness 185:24 user 185:9 uses 39:3 97:24 98:3 221:16 usually 226:16 227:11 utilization 37:6	v vacuum 157:18 valsartan 1:2 8:13 11:5 35:11,14,22 36:9,11 37:2,20,20 38:9 41:23 63:13 63:25 65:7,21 76:4,12,13,16,17 77:6,8,13,19,23 78:3,10,10 81:5 82:1,6 96:21 97:8 97:12,21 102:6 127:7,17 130:1,24 132:7,24,24 133:23,24 134:4 137:15,18 138:2,2 138:9 139:1,14 141:3,17,19,21 142:24 144:8,22 145:15 147:19 149:17 150:21 151:12 153:8 156:4,6 157:22 158:8,10,19 159:24 160:17,23 164:4 165:20 166:10 168:18 169:9 170:15,25 171:10,15,18 172:5,11,12,15,17 173:11,16 174:5 174:12,14,16,20 175:4,6,6,7,18,23 176:6,7,14 177:5,5 177:8,12 178:1,2,8 178:9 179:21 190:17 191:14 192:19 193:19 194:1,15 196:10 196:10 198:10 199:2,9,12,22
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RESTRICTED CONFIDENTIAL

[valsartan - went]

Page 43

205:10 213:2,4,5 213:10 214:11 215:17 218:18 226:11 227:9 229:7 230:13,15 231:3,14,18 232:5 232:17 233:20 236:8 237:5 238:6 238:15,23 239:17 240:5,19 241:2,8 243:4 244:1 245:1 valuable 137:14 187:3 value 111:11 114:24 116:6,12 117:10,23,25 118:7 119:2 133:7 137:4,13,18,22,22 138:13,18 140:8 140:15,21 141:4,9 141:23 142:2 143:1,7,11,12,17 143:19,21 144:4,9 144:23 145:8,9,14 145:23 146:1,6,10 146:15,15,17,18 146:18,19,23 147:25 148:12,14 148:18,25 149:3 151:23 152:8,16 152:19 153:6,11 153:14,18 164:4 164:15 183:10,13 183:13,15,25 184:1,3,4,7 185:10 185:23,25 186:1,1 186:10,12,12,13 186:15 201:18 204:12,16,23 230:12,12 232:23 233:3,13,19	values 145:21 vanaskie 100:7,25 variables 216:1 variation 162:25 variety 17:15,16 42:2 239:4 various 17:24 40:18 vast 228:25 vcds 154:3 verbally 11:23 verify 243:9 veritext 1:10 11:7 11:9 243:14,23 veritext.com 243:15 versus 26:6 73:4 veterans 218:8 video 11:3 94:22 94:25 95:2,7 241:12 videographer 7:8 11:1,7 57:13,16 58:15 74:6,9 76:23 77:2 90:9 91:22 92:1 94:17 94:24 95:11 112:21,25 150:13 150:16 180:9,13 206:8,11 235:13 235:17 241:13 videotaped 1:10 8:5,7 52:24 56:18 view 104:13 107:4 108:5 110:18 115:15 125:16,23 125:25 137:10,13 145:15 151:6 186:9,15,18 187:20,24 188:5 190:18 200:23	216:25 219:25 231:2,13 232:6,19 viewed 156:22 views 186:12 violation 84:9 105:22 106:4,12 106:25 107:23 108:4 110:20 189:10 violations 82:16 93:18 108:21 120:21 virtual 1:10 virtue 154:1 voices 147:1 volume 90:7,15 166:22 voluntary 175:10 vouchers 221:18 w w 3:4,5 wacker 4:5 wait 15:24,24 119:5 181:19,19 187:6,6,6,6,6 188:2 213:15,15 213:15,16 waiting 47:19,19 waive 12:1 waiver 180:20 waiving 32:16 34:17 154:24,25 155:15,16,23 walgreens 211:8 wallack 5:17 walnut 7:4 walsh 6:7 walshlaw.com 6:8 want 23:4 37:16 43:12,15,15 59:19 80:6 92:4,5 95:3,4	95:6 100:16,23 107:9 111:17 117:15 122:19 128:7,11 129:2 150:5 162:2 163:3 166:18 179:3 187:15 188:5,10 205:7 217:6 218:23 221:24 wanted 55:14 100:16 126:4 186:24 187:10 208:25 warning 93:23 warnings 139:12 washington 3:13 4:20 5:14 waste 54:18,19 95:3 wasting 111:20 way 2:13 12:24 26:22,24 31:10 37:14 55:1,7 80:6 97:15 100:15,24 117:25 143:19 145:8 146:11 149:4,15 151:22 153:11,13 162:15 163:24 194:20,21 202:6,24 208:13 212:11 225:9 226:7 242:11 ways 33:17 93:24 135:6 141:15 192:17 193:24 we've 33:11 57:20 182:9 183:13 web 184:15 week 17:19 73:15 went 171:1,1 187:23 192:20,21
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RESTRICTED CONFIDENTIAL

[went - worry]

Page 44

194:16 west 4:5 5:4 6:18 6:24 wharton 23:25 whereof 242:13 whiteley 2:20,21 28:13 whitely 59:13 whitney 6:17 widely 16:10 william 5:17 184:20,25 185:4 willing 157:13,14 161:8,21 163:7,9 winter 60:1 wish 101:16 withdraw 62:2 94:15 112:5,6 withdrawing 55:18,18 withstanding 13:12 witness 2:5 11:12 11:22 12:6 14:25 16:18 20:9,12 21:2 26:6 28:19 28:21,25 30:11,22 32:8,15,19 33:3,6 34:20 35:20 36:15 38:5 42:18,22 44:10 45:7,15 46:4 47:8,12 49:11 52:13 53:22 57:9 58:18 61:10 61:22,25 65:17 69:16 70:2,20 71:10 75:21 76:20 77:12,21 82:12 83:6 85:1 86:20 86:21 88:22 89:9 89:22 90:4,12,22	92:16 93:22 94:3 94:11 96:7,11,23 97:11,24 98:24 99:10,10,16,21 100:5,18 101:3,5 101:19 102:10 103:2,18 104:11 105:18 106:4,16 107:7,19 108:1,8 108:24 109:4,7,13 110:6,25 112:2,7 112:12,16,20 114:14 115:4,11 115:20 116:8,15 117:7,13 118:21 119:5 121:4 123:1 125:22 126:19 127:11,22 128:1,3 128:6,19 129:16 129:17 130:5 131:5 132:1,11,19 133:19 134:11 135:2,11,18 136:9 136:20,23 137:7 137:21 138:5,21 139:5,18,23 140:3 140:11,17,25 141:6 142:1,5,10 142:13,17 143:5 143:15,25 144:2 145:2,4,19 146:22 147:4,12,23 148:22 149:24 151:1,20 152:15 153:10,24 154:16 155:2,18,25 156:11 157:9 158:5,14,23 159:11 160:5,20 161:11,25 163:13 163:23 164:6,19	165:15,24 166:13 168:5 169:22 170:5,19 171:18 171:25 172:22 173:14 175:1 176:5,23 177:20 178:13,25 179:8 179:19 180:23 181:5,14 182:25 184:9 185:1 186:18 188:23 189:1,14 190:23 191:20 192:10,15 193:4,14,22 194:11 195:2,23 196:5,17 198:18 199:7 200:6,20 201:6 203:5,16,23 205:2,5,12,24 206:4 207:16,25 208:6 209:15 211:13 212:9,17 212:19,22 214:14 215:12,20 216:21 219:2,21 220:5,11 220:19 223:14 224:6,17 225:21 226:6 227:5 228:8 228:19,24 231:6 232:10,22 233:9 233:12,23 234:15 237:7 238:9,17 239:2,21 240:12 240:25 242:6,13 243:8,10,12,19 witnesses 87:6,25 100:9,10 wmurtha 5:18 woefully 70:11 word 46:24 120:6 128:6 139:21	234:22 wording 176:9 words 80:8 117:2 117:23 128:9 156:19 159:2 183:16 190:7 195:4 work 17:11 18:13 18:17 19:5,9,10,17 19:24 20:13 21:21 21:24 22:7,7 24:13,18,19 26:6 26:10,19,21 29:9 30:3 32:20,21 33:8 39:10 40:2 42:9 45:11 46:21 46:22 48:9,19 50:16 51:21 53:21 63:13 65:13,16 66:9 69:13 71:3 180:21 worked 16:22 19:21 21:8 24:7 25:1,23 26:16 29:6 45:17 46:10 48:6,11,14 50:9 52:1 53:25 61:12 63:25 70:13 workers 218:13 working 17:24,25 19:14,19 20:4 24:4 25:13 26:24 29:18 31:3,16 33:12 47:25,25 59:24 62:25 72:3 86:5 works 50:7 world 112:8 190:19 193:23 worry 67:9
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RESTRICTED CONFIDENTIAL

[worth - zoom]

Page 45

worth 145:9 151:23 152:8	207:25 241:11
worthless 114:25 115:1,18 122:23 124:6 125:18 126:16 145:16 151:7 153:25 156:24 204:5 230:16,17 232:7 232:18	year 17:23 26:5,13 47:4 73:16 209:9 212:14 214:18 215:21 216:9 yearly 106:22 years 15:3,17 17:2 19:22 22:3 26:16 202:16 204:20 york 2:18,18 6:19 6:19 73:14
worthlessness 115:17 145:10 151:9 153:15 185:24	z
write 15:13 157:13 201:17 writing 15:15 47:21 50:17 writings 54:5 written 122:16 212:1 wrongdoing 203:1 wrote 51:2,4,6,20 52:1 82:19,21	zero 201:18 zhejiang 78:1 93:13,20 168:22 zhejiant 3:8,15 zhp 12:18 93:21 93:21,22,23 168:18,19 zmick 6:23 zoom 1:10
x	
x 1:2,5 8:1 xi01658 242:17 xponent 66:4 210:15,24 211:15 212:2,6,25 215:3 217:14,20	
y	
yeah 18:7 19:12 27:3 34:2 43:22 49:19 57:2 60:4,4 60:18 70:25 109:15 134:15 137:9 138:5 157:2 159:18 166:25 168:20 176:18	

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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Exhibit 48

REDACTED

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

- - - - - x
IN RE: VALSARTAN, LOSARTAN, AND : MDL NO. 2875
IRBESARTAN PRODUCTS LIABILITY :
LITIGATION, :
:
THIS DOCUMENT RELATES TO :
ALL ACTIONS :
- - - - - x

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Veritext Virtual Zoom Videotaped
deposition of RENA M. CONTI, Ph.D., taken on Friday,
February 11, 2022, in Glenside, Pennsylvania,
commencing at 9:04 a.m. Eastern Standard Time,
before Jamie I. Moskowitz, a Certified Court
Reporter and Certified Livenote Reporter.

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<p style="text-align: right;">Page 10</p> <p>1 TABLE OF CONTENTS</p> <p>2 RENA M. CONTI, Ph.D.</p> <p>3 Examination</p> <p>4 By Ms. Kapke.....Page 11</p> <p>5 By Mr. Campbell.....Page 100</p> <p>6 By Mr. Ostfeld.....Page 182</p> <p>7 Index of Exhibits.....Page 8</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 12</p> <p>1 A Yes.</p> <p>2 Q What did you review?</p> <p>3 A My report.</p> <p>4 Q Anything else?</p> <p>5 A I looked up some statistics regarding</p> <p>6 the revenues of retailers and wholesalers in this</p> <p>7 case.</p> <p>8 Q Statistics from your report or</p> <p>9 statistics that were independent of references in</p> <p>10 your report?</p> <p>11 A The shareholder reports of the -- the</p> <p>12 retailers and the wholesalers.</p> <p>13 Q So, like, the 10-Ks?</p> <p>14 A Correct.</p> <p>15 Q Okay. Okay. Gotcha.</p> <p>16 And I -- I honestly don't remember</p> <p>17 that. Are those cited in your report? Are the --</p> <p>18 are retailers' --</p> <p>19 A No, they're not. No, they're not.</p> <p>20 But there -- there are things that I do very</p> <p>21 typically when I'm preparing for a deposition.</p> <p>22 They're public. They're also things that I -- I</p> <p>23 spend time teaching, using. In fact, some of the</p> <p>24 defendants in this case are companies that my class</p> <p>25 on Strategy in the Pharmaceutical Industry is</p>
<p style="text-align: right;">Page 11</p> <p>1 THE VIDEOGRAPHER: The time is 9:04.</p> <p>2 This begins Media Unit Number 1. We're back on</p> <p>3 the record.</p> <p>4 MR. GOLDBERG: Good morning, Doctor.</p> <p>5 This is Seth Goldberg, again. I'm not on</p> <p>6 video. I will be momentarily. But at this</p> <p>7 point, I'm going to pass the witness to the</p> <p>8 next questioning counsel. I am not concluding</p> <p>9 my questioning, but in the interest of time, I</p> <p>10 want to give other counsel an opportunity to</p> <p>11 ask questions.</p> <p>12 THE COURT REPORTER: Kara, you're on</p> <p>13 mute.</p> <p>14 EXAMINATION BY MS. KAPKE:</p> <p>15 Q Good morning, Dr. Conti. My name is</p> <p>16 Kara Kapke. I represent CVS and Rite Aid, and I'm</p> <p>17 going to be asking you questions primarily about</p> <p>18 your opinions vis-a-vis the retail pharmacy</p> <p>19 defendants.</p> <p>20 My first question is, do you</p> <p>21 understand that you're still under oath here today?</p> <p>22 A Yes.</p> <p>23 Q Great. Did you review any documents</p> <p>24 or materials last night or this morning before</p> <p>25 starting today's deposition?</p>	<p style="text-align: right;">Page 13</p> <p>1 currently studying, so part of my review was to get</p> <p>2 ready for my class on Monday.</p> <p>3 Q Got it. Okay.</p> <p>4 Did you -- we talked about, yesterday,</p> <p>5 you not reviewing any depositions, and I wanted to</p> <p>6 confirm that you have not reviewed any depositions</p> <p>7 of retailer pharmacy witnesses in this case; is that</p> <p>8 correct?</p> <p>9 A That's correct.</p> <p>10 Q Did you review any deposition exhibits</p> <p>11 from the depositions of the retail pharmacy 30(b)(6)</p> <p>12 witnesses?</p> <p>13 A Why don't we check my Appendix B?</p> <p>14 There's a lot of documents, so, let's just check.</p> <p>15 So there is a declaration -- so are</p> <p>16 you asking for declarations? Is that correct?</p> <p>17 Q I'm asking if you reviewed any</p> <p>18 written -- any -- strike that.</p> <p>19 I'm asking if you reviewed any</p> <p>20 deposition exhibits from the depositions of the</p> <p>21 retail pharmacy deponents.</p> <p>22 A No, I did not, not that I'm aware of.</p> <p>23 Q How about any meet and confer letters</p> <p>24 or correspondence from -- from counsel for the</p> <p>25 retail pharmacy defendants?</p>

<p style="text-align: right;">Page 14</p> <p>1 A No.</p> <p>2 Q Have you reviewed any opinions</p> <p>3 relating to discovery from Special Master</p> <p>4 Judge Vanaskie or Judge Schneider?</p> <p>5 THE COURT REPORTER: Or Judge...</p> <p>6 MS. KAPKE: Schneider.</p> <p>7 THE COURT REPORTER: Okay.</p> <p>8 THE WITNESS: There's a weird echo,</p> <p>9 and I didn't hear half your sentence. I'm</p> <p>10 sorry.</p> <p>11 BY MS. KAPKE:</p> <p>12 Q No, that's okay.</p> <p>13 Have you reviewed any opinions</p> <p>14 relating to discovery from Special Master</p> <p>15 Judge Vanaskie or Judge Schneider?</p> <p>16 A No. All I know is that I have very</p> <p>17 limited data -- limited data from the retailers.</p> <p>18 Q And you mentioned yesterday that you</p> <p>19 read one of Judge Kugler's opinions in -- in this</p> <p>20 case. What opinions of Judge Kugler's have you read</p> <p>21 for purposes of this litigation?</p> <p>22 A Just what I read to you -- you all</p> <p>23 yesterday.</p> <p>24 Q Okay. Did you read the entire opinion</p> <p>25 that -- that the snippet that you read yesterday</p>	<p style="text-align: right;">Page 16</p> <p>1 THE COURT REPORTER: I'm sorry,</p> <p>2 Walgreens...</p> <p>3 THE WITNESS: Walgreens and the</p> <p>4 University of Chicago had a long-standing data</p> <p>5 collaborative, and I was in charge of that data</p> <p>6 collaborative. I wrote several papers with the</p> <p>7 head of public economics at Walgreens when I</p> <p>8 was faculty there.</p> <p>9 THE THE COURT REPORTER: When you were</p> <p>10 faculty there?</p> <p>11 THE WITNESS: When I was faculty at</p> <p>12 the University of Chicago.</p> <p>13 BY MS. KAPKE:</p> <p>14 Q Did you rely on the data that you</p> <p>15 reviewed in your faculty life relating to Walgreens</p> <p>16 and CVS for purposes of your opinions in this</p> <p>17 matter?</p> <p>18 A Well, so we talked about this</p> <p>19 yesterday. I primarily am a researcher, and I teach</p> <p>20 about the pharmaceutical industry. And so the</p> <p>21 papers that I wrote with Walgreens data are in my</p> <p>22 CV. They're listed. And to the extent that I know</p> <p>23 something about how these pharmacies are collecting</p> <p>24 information, what data they have on dispensing</p> <p>25 prescriptions, is -- is informed both by the work</p>
<p style="text-align: right;">Page 15</p> <p>1 came from, or just a portion of it?</p> <p>2 A I read the full paragraph that that</p> <p>3 portion I read came from, but that's it.</p> <p>4 Q Okay. I -- I want to turn to your</p> <p>5 report, Conti Exhibit 5, and Attachment B, which we</p> <p>6 just talked about. And on Pages 4 to 8 of the</p> <p>7 attachment, under the heading "Electronic Data," and</p> <p>8 then the subheading, "Retailer Claims Data," you</p> <p>9 have a listing of specific documents relating to</p> <p>10 retail pharmacy defendants that you reviewed,</p> <p>11 correct?</p> <p>12 A Yes.</p> <p>13 Q Is it okay if I refer to that group of</p> <p>14 data by the subheading "Retailer Claims Data"?</p> <p>15 A Sure.</p> <p>16 Q Okay. I -- I just want to make sure</p> <p>17 that you'll understand that if I'm referring to</p> <p>18 retailer claims data that that's what I'm referring</p> <p>19 to. B -- go ahead.</p> <p>20 A Okay. Yeah. Just one thing that I</p> <p>21 should tell you is that -- so in my research, I have</p> <p>22 spent a fair amount of time working with data from</p> <p>23 CVS and also from Walgreens, specifically the</p> <p>24 Walgreens -- Walgreens and the University of Chicago</p> <p>25 had --</p>	<p style="text-align: right;">Page 17</p> <p>1 that I do in research, but also the work that I've</p> <p>2 done in --</p> <p>3 BY MS. KAPKE: That you've done in...</p> <p>4 THE WITNESS: This particular matter.</p> <p>5 BY MS. KAPKE:</p> <p>6 Q In terms of the actual calculations</p> <p>7 you made, not in your opinions, but the actual</p> <p>8 calculations that you made, did you rely on any of</p> <p>9 that, I'll call it faculty data, or did you solely</p> <p>10 rely on the retailer claims data?</p> <p>11 A I relied on the retailer claims data</p> <p>12 that was provided to me in this matter to do my</p> <p>13 calculation. But I have a broader understanding of</p> <p>14 what is collected by the retail pharmacies that</p> <p>15 included the ones that are named in this matter.</p> <p>16 Q Okay.</p> <p>17 A Due --</p> <p>18 THE COURT REPORTER: I'm sorry?</p> <p>19 THE WITNESS: Due to the research that</p> <p>20 I have done with them.</p> <p>21 BY MS. KAPKE:</p> <p>22 Q Understood.</p> <p>23 The documents listed here for the</p> <p>24 retailer claims data are not identified by a Bates</p> <p>25 number, but is it your understanding that the</p>

<p style="text-align: right;">Page 18</p> <p>1 documents referenced there are the documents 2 produced by the retail pharmacy defendants in this 3 litigation with Bates numbers? 4 A That is my understanding. 5 MS. KAPKE: I'm going to introduce, 6 and mark as Conti Exhibit 7, the retailer 7 damages output Excel spreadsheet file from the 8 materials that you provided. And it's on the 9 screen. And for the record -- 10 (Whereupon, Exhibit Conti 7 was marked 11 for Identification.) 12 THE WITNESS: Can you refer me to a 13 specific one? 14 BY MS. KAPKE: 15 Q I'm sorry. What? 16 A Can you refer me to the specific 17 output that's listed on my Exhibit B? 18 Q This is the retailer damages output 19 Excel spreadsheet that you provided. 20 A I'm asking you, is it the backup, or 21 is it one of the documents that is listed -- 22 Q It's the backup. 23 A -- in Exhibit B. I can't hear you. 24 I'm sorry. 25 Q So if you -- this is something that</p>	<p style="text-align: right;">Page 20</p> <p>1 BY MS. KAPKE: 2 Q So I'm marking it Conti Exhibit 7. 3 You, in the materials provided to us, labeled it, 4 entitled it "Retailer Damages Output." 5 A But for -- for unjust enrichment or 6 liability? 7 Q You did not make a distinction in what 8 materials were sent to us. 9 A I see. Well, I'm going to have to 10 double check with my staff then, please. 11 Q What are you double checking? 12 A Whether this is this for the liability 13 claims or for the unjust enrichment calculation. 14 Q Is it your suggestion that you have 15 two spreadsheets -- a backup data for those? 16 A No. As I testified yesterday, the 17 unjust enrichment and liability estimates are 18 slightly different. You can see that in my Table 2 19 and Table 3 of my report. And -- and the difference 20 is largely related to the inclusion or exclusion of 21 specific states. 22 There is no indicator here for 23 whether -- for when the state is indicated for which 24 calculation. And so I just want to double check 25 with my staff. And I --</p>
<p style="text-align: right;">Page 19</p> <p>1 you derived, and you -- I'm -- I'm not sure I 2 understand your -- 3 A I'm asking, is this the backup that we 4 provided to you, or is it one of the documents that 5 you listed here -- I'm sorry -- that I listed here 6 in Exhibit B? 7 Q No. This is the backup that you 8 provided to us. 9 A Just wanted to make sure. 10 Q Yes. And so I will represent for the 11 record that this spreadsheet has 3,741 rows, and as 12 you can see -- 13 MS. KAPKE: Maybe it can be made a 14 little bit larger. 15 BY MS. KAPKE: 16 Q There are five columns across the top 17 reading retailer, entity, state, product name and 18 consumer impact. Do you -- 19 A Okay. 20 THE WITNESS: Can we -- can we scroll 21 all the way down so I can see -- make sure that 22 this is actually a full document, please? 23 Keep on going. Okay. Okay. So just 24 give me a second. And this is for -- the 25 backup for which exhibit?</p>	<p style="text-align: right;">Page 21</p> <p>1 Q I'm -- and I'm sorry. I'm not trying 2 to be difficult. I just don't understand what you 3 need to double check. 4 A All I want to know is whether this 5 backup is for the liability or for the unjust 6 enrichment calculations. That's all. 7 You'll see there's Table 2. 8 Q Right. 9 A Then there's Table 3. And they 10 are -- there's two theories of liability for 11 Table 2. They differ underlying Table 2. And then 12 in Table 3, there's an unjust enrichment 13 calculation. And each one in the series of damages 14 vary slightly for the retailers, related to what 15 states are included, which are not listed here. 16 Q Right. Let's' -- we'll -- we'll get 17 to that. 18 Was there any dispensing or 19 prescription data that went into the creation of 20 this spreadsheet besides the retailer claims data? 21 A I don't understand your question. I'm 22 sorry. 23 Q Was there any prescription data or 24 dispensing data or any other data that went into the 25 creation of this output file, besides what we talked</p>

<p style="text-align: right;">Page 22</p> <p>1 about earlier, being the retailer claims data?</p> <p>2 A Well, how do you define prescription</p> <p>3 data versus claims data versus dispensing data? I'm</p> <p>4 not -- I'm not familiar with those -- those are not</p> <p>5 terms of art.</p> <p>6 Q Okay. That's -- that's fair. And</p> <p>7 that's a bad question. Thank you for pointing out a</p> <p>8 bad question.</p> <p>9 I'm just trying to figure out if</p> <p>10 there's any data that you used to generate this</p> <p>11 spreadsheet besides what we talked about, being</p> <p>12 retailer claims data?</p> <p>13 A So my understanding is that the</p> <p>14 retailers provided my staff a -- data on spending by</p> <p>15 consumers for the at-issue products by state, month</p> <p>16 and year, and product -- and product subcategory,</p> <p>17 really NDC code. And that they represented, the</p> <p>18 retailers, that the dispensing fee, which I think is</p> <p>19 what you've referred to by "dispensing data," was</p> <p>20 already taken out, as was the payment made by the</p> <p>21 third-party payor --</p> <p>22 Q Okay. I --</p> <p>23 A -- for the insured prescriptions.</p> <p>24 Q I think we're talking past each other,</p> <p>25 because my -- my question just relates to, are there</p>	<p style="text-align: right;">Page 24</p> <p>1 were dispensed.</p> <p>2 All we had was the information that</p> <p>3 was provided to us.</p> <p>4 BY MS. KAPKE:</p> <p>5 Q That's -- that's what I'm trying to --</p> <p>6 to make sure I understand.</p> <p>7 When you generated this output file,</p> <p>8 did you rely on anything other than what was</p> <p>9 provided to you?</p> <p>10 A We relied on the names and NDC codes</p> <p>11 and time periods of the at-issue valsartan and other</p> <p>12 products.</p> <p>13 Q Okay. And that -- that makes sense.</p> <p>14 Am I correct that this spreadsheet was</p> <p>15 created using the SAS software?</p> <p>16 THE COURT REPORTER: Using the what?</p> <p>17 MS. KAPKE: The SAS software.</p> <p>18 THE WITNESS: Do you mean SAS?</p> <p>19 BY MS. KAPKE:</p> <p>20 Q Yes.</p> <p>21 A I don't know. Bennett programs in SAS</p> <p>22 and in SETA. And also, as you can see, this is an</p> <p>23 Excel file. So he may have actually done this</p> <p>24 calculation in -- in Excel.</p> <p>25 Q I want to talk about the relevant time</p>
<p style="text-align: right;">Page 23</p> <p>1 any -- any prescriptions, any fills, any -- I'm not</p> <p>2 talking about individual fees. I'm just talking</p> <p>3 about to, generate this spreadsheet, did you use any</p> <p>4 type of document other than what's in the retailer</p> <p>5 claims data?</p> <p>6 THE COURT REPORTER: Did you use any</p> <p>7 other type of...</p> <p>8 MS. KAPKE: Document.</p> <p>9 THE WITNESS: I have -- honestly, I</p> <p>10 don't think I understand what you're saying at</p> <p>11 all. So retailer pharmacies are sitting on an</p> <p>12 incredible amount of data. So I think, you</p> <p>13 know, there's millions of transactions that are</p> <p>14 being done, all across the United States, every</p> <p>15 single day, dispensed drugs.</p> <p>16 What we were provided by the retailer</p> <p>17 pharmacies in this setting were very simple.</p> <p>18 There were co-insurance and co-payment,</p> <p>19 customer-paid amounts by product, manufacturer,</p> <p>20 month and year and state. They took out the</p> <p>21 dispensing fees, which are usually charged when</p> <p>22 a consumer goes and fills a prescription, and</p> <p>23 the retailer pharmacies also took out the</p> <p>24 payments that were made by the commercial</p> <p>25 insurers when these -- when these prescriptions</p>	<p style="text-align: right;">Page 25</p> <p>1 period used to generate this exhibit. It's my</p> <p>2 understanding, from your report, that you did not</p> <p>3 include any bills after the month of recall; is that</p> <p>4 correct?</p> <p>5 A After the final month of recall for</p> <p>6 each at-issue product. That's why the name of the</p> <p>7 manufacturer and the product name at the NDC code</p> <p>8 was so critical in our analysis. And what I already</p> <p>9 mentioned, we used -- we used the date. We used the</p> <p>10 month and year, plus the manufacturer and the</p> <p>11 product name for each of our assessments.</p> <p>12 Q And for bills of Hetero NDCs, you did</p> <p>13 not include any bills before May 2018, correct?</p> <p>14 A Correct. And we stopped at</p> <p>15 August 2018.</p> <p>16 Q Logistically, how did you filter out</p> <p>17 those dates? Was that something Bennett did?</p> <p>18 A Again, retail pharmacies provided the</p> <p>19 data to us by month and year for every single</p> <p>20 product and defined by NDC code, manufacturer and</p> <p>21 state. It was the month variable that was provided</p> <p>22 to us that allowed us to filter and confine it to</p> <p>23 the specific time periods.</p> <p>24 Again, pharmacies are -- in the</p> <p>25 United States, such as the ones listed here, are</p>

<p style="text-align: right;">Page 26</p> <p>1 at-issue here, are sitting on daily transactions</p> <p>2 with a -- literally with a hour, minute stamp</p> <p>3 associated with them.</p> <p>4 Q Okay. But --</p> <p>5 A Hold on.</p> <p>6 So if -- my understanding is that the</p> <p>7 information that was provided to us was aggregated</p> <p>8 by the retail pharmacies themselves, up into a</p> <p>9 particular time period, and then provided to us.</p> <p>10 They could have given us the disaggregated data at</p> <p>11 literally the minute, hour, second time period, if</p> <p>12 they wanted to, so.</p> <p>13 Q Okay. But that wasn't my question.</p> <p>14 My question was how -- how you or your</p> <p>15 staff took the retailer claims data and turned it</p> <p>16 into this output file, not -- not the inceptions</p> <p>17 underlying that.</p> <p>18 A I answered that question. So I told</p> <p>19 you we acquired information with month, year,</p> <p>20 product -- product, NDC -- identified at the NDC</p> <p>21 code level and the manufacturer and the state. What</p> <p>22 we did was simply aggregate that information up</p> <p>23 after limiting it to the relevant time period for</p> <p>24 each specific product.</p> <p>25 Q Let's go to your --</p>	<p style="text-align: right;">Page 28</p> <p>1 that in the paragraph just referenced.</p> <p>2 Q Yeah. Sorry about that.</p> <p>3 A Let me just make sure I'm on the same</p> <p>4 page with you.</p> <p>5 Q It is on the screen now, if that's</p> <p>6 helpful.</p> <p>7 A Yeah. I prefer -- prefer the paper,</p> <p>8 but thank you. So, right. And then there is a</p> <p>9 footnote -- a footnote -- so there's a footnote that</p> <p>10 ends that paragraph, which is 63. And that -- that</p> <p>11 refers back to Footnote 3, as I mentioned in the</p> <p>12 beginning of my report. And then in the beginning</p> <p>13 of my report, I reference the complaint, and then go</p> <p>14 onto reference the at-issue products.</p> <p>15 Q And --</p> <p>16 A Excuse me. And their time period.</p> <p>17 Q And -- and my question is, are the</p> <p>18 relevant time periods the same for paragraphs 60 and</p> <p>19 63?</p> <p>20 A Yes. The time periods relate to the</p> <p>21 sale of prescription drugs from the relevant</p> <p>22 manufacturers in the relevant time period as</p> <p>23 enumerated in Footnote 3 and discussed in the</p> <p>24 complaint. I do not make a distinction between</p> <p>25 manufacturer and retailer.</p>
<p style="text-align: right;">Page 27</p> <p>1 THE WITNESS: There -- there's, like,</p> <p>2 a very loud stomping, or something else, noise,</p> <p>3 in the background. It's very hard to hear. It</p> <p>4 sounds like it stopped now.</p> <p>5 BY MS. KAPKE:</p> <p>6 Q Okay. I want to go back to your</p> <p>7 report, Conti Exhibit 5. In paragraph 60, you state</p> <p>8 that "Expenditures by plaintiffs for the at-issue</p> <p>9 valsartan products can be expressed as the product</p> <p>10 of price and quantity over the relevant time period</p> <p>11 of the alleged misconduct."</p> <p>12 I want to ask you about the phrase</p> <p>13 "time period of the alleged misconduct." What</p> <p>14 misconduct are you referring to, if any, on the part</p> <p>15 of the retail pharmacy defendants?</p> <p>16 A What I was asked to assume and what</p> <p>17 was outlined in the complaint that I reference in</p> <p>18 the first couple of paragraphs of my report.</p> <p>19 Q For unjust enrichment, you defined the</p> <p>20 time period as each at-issue valsartan product sold</p> <p>21 by the defendant retailers from January 1st, 2012</p> <p>22 until the at-issue valsartan products were recalled</p> <p>23 in 2018 and 2019 for being adulterated and</p> <p>24 misbranded. That's in paragraph 63.</p> <p>25 A Yeah. I was going to say, I don't see</p>	<p style="text-align: right;">Page 29</p> <p>1 Q Got it.</p> <p>2 MS. KAPKE: Okay. I want to go back</p> <p>3 to Conti Exhibit 7, the output file.</p> <p>4 BY MS. KAPKE:</p> <p>5 Q I think I understand what each of</p> <p>6 these columns represent, but I just want to go</p> <p>7 through and double check that my understanding is</p> <p>8 correct.</p> <p>9 So Column A is going to represent the</p> <p>10 retail pharmacy defendants in this case, correct?</p> <p>11 A That's what is listed, sure.</p> <p>12 Q Okay. And then Column B will</p> <p>13 represent the manufacturer defendants at-issue in</p> <p>14 the case, which you identified through the NDC code,</p> <p>15 correct?</p> <p>16 A Well, it's -- it's listed from this</p> <p>17 FDA recall list, the manufacturer.</p> <p>18 Q Okay. To -- when you were processing</p> <p>19 the retailer claims data to create this output file,</p> <p>20 did you exclude any prescription fills in the</p> <p>21 retailer claims data based on NDC codes?</p> <p>22 A Yes, I already discussed this</p> <p>23 yesterday. There were some -- we -- I was provided,</p> <p>24 from attorneys, the list of manufacturers and NDC</p> <p>25 codes from the FDA recall list, and then some of the</p>

Page 30

1 NDCs were also -- that were at-issue, were
 2 repackaged, relabeled or privately labeled by
 3 manufacturers downstream. That happens actually
 4 quite frequently in the -- in the U.S. market. We
 5 picked up those NDC codes and included them here.
 6 Q Did you exclude any prescription
 7 fills?
 8 A We didn't have prescription fill data.
 9 You did not -- that's not what you gave us. We had
 10 aggregate sales to specific consumers, paid by
 11 co-pays and co-insurance. Fills are much larger --
 12 or contain a lot more information, but you did not
 13 provide that information. Fills, again, provide the
 14 dispensing fee, whether or not the individual used
 15 their insurance to pay for a portion or the entirety
 16 of the prescription, the date, the time, of the
 17 dispensing. It could include the -- the name of the
 18 customer, their address, and on and on. We
 19 didn't -- we didn't have that aggregate of data.
 20 You did not provide that to us.
 21 Q How much time did you spend looking at
 22 the actual retailer claims data?
 23 A I spent some time with my staff.
 24 Q What does that mean?
 25 A I spent some time with my staff.

Page 31

1 Q What does "some time" mean?
 2 A I spent some time over the course of
 3 the time that I was working on this case. In
 4 addition, I spoke with my staff on a regular basis
 5 about the analysis that they were doing at my
 6 direction.
 7 Q Did you --
 8 A That's kind of the normal course of
 9 doing research and also working on these cases, is
 10 that we look at data that was provided. We clean
 11 and double check the completion of the data. We
 12 look to see what fields are provided. We look to
 13 see what fields were not provided that we would
 14 expect to provide -- to be provided. We do some
 15 double checks to make sure there's not missing data,
 16 and if there is missing data, how do we think about
 17 that, and on and on. That's all part of the process
 18 of doing the work that I do every day.
 19 Q Did you, yourself, ever open an actual
 20 spreadsheet in the retailer claims data?
 21 A No, but Bennett and the rest of my
 22 staff opened it. And we discussed it at length and
 23 multiple times -- and over multiple times, over the
 24 time period of this analysis.
 25 Q Column C of Exhibit 7 is the state at

Page 32

1 issue, correct?
 2 A It lists the state.
 3 Q Correct. And your report, at
 4 paragraph 78 --
 5 MS. KAPKE: And we can go --
 6 THE WITNESS: Hold on. Hold on,
 7 paragraph 78.
 8 MS. KAPKE: -- to that.
 9 THE WITNESS: Paragraph 78. Okay.
 10 Just give me a second to read. Okay.
 11 BY MS. KAPKE:
 12 Q It discusses how you used the state in
 13 which the retail pharmacy was located for -- I
 14 assume you're talking about physical brick and
 15 mortar stores at that -- at that point, correct?
 16 A I'm assuming.
 17 Q And then for mail order pharmacy
 18 claims, you used the state where the prescription
 19 was mailed. Does that mean the state where the
 20 prescription was mailed to or where it was mailed
 21 from?
 22 A It was mailed to because, again,
 23 injury occurs at the point of sale. So for retail
 24 pharmacies, the dispensed prescription is the
 25 location of the injury. And for mail order, it's

Page 33

1 the -- where the -- the prescription was mailed to.
 2 Q How did you and your staff group
 3 particular fills to particular states to derive that
 4 output file?
 5 A It is contained -- the state is
 6 contained in the information -- in the information
 7 that the retailers provided to us.
 8 Q What did you or your staff do when the
 9 Excel spreadsheet and the retailer claims data left
 10 the state field blank?
 11 A I don't recall. And I don't know
 12 the -- the occurrence of that. Again, I'm more than
 13 happy to check with my staff.
 14 Q Well, today is my -- my opportunity to
 15 depose you about the contents of your report. So
 16 what did you or your staff do when an Excel
 17 spreadsheet in the retailer claims data used a
 18 question mark in the state field?
 19 A I'm not aware that that was -- yeah,
 20 I'm not aware that that was -- that occurred at all.
 21 Q Same question if an abbreviation "AA"
 22 was used in the state field?
 23 A Again, I'm not aware that that
 24 occurred at all or at what frequency it occurred.
 25 If it did, my assumption is that --

<p style="text-align: right;">Page 34</p> <p>1 THE THE COURT REPORTER: Is that what?</p> <p>2 THE WITNESS: That it was excluded,</p> <p>3 those scripts were excluded.</p> <p>4 BY MS. KAPKE:</p> <p>5 Q Does the abbreviation "AA" mean</p> <p>6 anything to you?</p> <p>7 A It does not, and I've never</p> <p>8 encountered it in any of the research work I've</p> <p>9 done.</p> <p>10 Q How about the abbreviation "AE"?</p> <p>11 A Same. But, again, I suspect that</p> <p>12 those were excluded for my analysis. Without a</p> <p>13 state attribution that actually means something, I</p> <p>14 don't -- I wouldn't feel comfortable including that</p> <p>15 information. I'm a little Type A about data</p> <p>16 analysis, as you probably have -- have surmised.</p> <p>17 MS. KAPKE: I want to go back to</p> <p>18 Exhibit 7.</p> <p>19 BY MS. KAPKE:</p> <p>20 Q Column D is the product name. That --</p> <p>21 the product name is just derived from the NDC --</p> <p>22 A I -- I don't know what you're talking</p> <p>23 about, and you have --</p> <p>24 Q Yeah.</p> <p>25 A Okay. Thank you.</p>	<p style="text-align: right;">Page 36</p> <p>1 was appropriate -- strike that.</p> <p>2 I want to go back and talk about when</p> <p>3 you included fills.</p> <p>4 A I don't know what you mean by "fills,"</p> <p>5 ma'am.</p> <p>6 Q Okay. That's -- that's fair. Thank</p> <p>7 you for -- for clarifying that. Did you -- I'll</p> <p>8 strike that and ask a different question.</p> <p>9 Did you ask plaintiffs' counsel</p> <p>10 whether it was appropriate to assume that the data</p> <p>11 in -- provided by the retail pharmacy defendants in</p> <p>12 the retailer claims data were actually filled at one</p> <p>13 of the defendant pharmacies?</p> <p>14 A I don't understand your question. I'm</p> <p>15 sorry.</p> <p>16 Q Did you ask plaintiffs' counsel --</p> <p>17 I'll ask it again.</p> <p>18 Did you ask plaintiffs' counsel about</p> <p>19 any limitations in the retailer claims data?</p> <p>20 A I mean, there are significant</p> <p>21 limitations in the claims data that was provided to</p> <p>22 me. So again, dispensing fees were not included.</p> <p>23 Nor were the payments made by the insurer. Nor were</p> <p>24 any information provided about whether or not these</p> <p>25 patients were insured at all. Nor was any</p>
<p style="text-align: right;">Page 35</p> <p>1 So I'm sorry. This is -- I'm sorry.</p> <p>2 I didn't hear the last -- is that -- was that a</p> <p>3 question or a statement?</p> <p>4 Q I'm just asking you to confirm that</p> <p>5 the product name is derived from the NDC code.</p> <p>6 A Yes.</p> <p>7 Q Okay. And then I want to talk about</p> <p>8 Column E, the customer impact column.</p> <p>9 A That's not what it says, ma'am.</p> <p>10 Q Oh, I'm sorry. Consumer. My -- my</p> <p>11 apologies. Thank you.</p> <p>12 The consumer impact column. To derive</p> <p>13 that, you would total the full patient paid amount</p> <p>14 for each qualifying prescription for the particular</p> <p>15 retailer, manufacturer, state and script; is that</p> <p>16 correct?</p> <p>17 A Correct. And year -- and -- and time.</p> <p>18 Q And relevant time period. And that is</p> <p>19 just simple addition, correct?</p> <p>20 A So it's aggregated over quantity and</p> <p>21 paid amount.</p> <p>22 Q The -- there's -- the aggregation is</p> <p>23 just adding numbers up, correct?</p> <p>24 A Well, it's -- sure.</p> <p>25 Q Okay. I want to go back to when it</p>	<p style="text-align: right;">Page 37</p> <p>1 other -- I mean, there's -- again, retail pharmacies</p> <p>2 are sitting on tons of data that they collect when</p> <p>3 they're dispensing prescriptions. We were provided</p> <p>4 very limited data, considering the universe of data</p> <p>5 that they have registered and are required to have</p> <p>6 when they're dispensing prescription drugs in the</p> <p>7 U.S. chain.</p> <p>8 Q Did you ask plaintiffs' counsel to ask</p> <p>9 for additional data?</p> <p>10 A We had discussions about what</p> <p>11 was -- what was the data that we wanted very early</p> <p>12 on in this case, given the theories of liability and</p> <p>13 damage, which included some of the information that</p> <p>14 I provided -- I enumerated to you.</p> <p>15 Q Did you ask plaintiffs' counsel to</p> <p>16 confirm to you that the data produced by the retail</p> <p>17 pharmacy defendants in the retailer claims data only</p> <p>18 reflected prescriptions that were actually filled at</p> <p>19 a defendant pharmacy?</p> <p>20 A That was always represented to us as</p> <p>21 being provided by the retail pharmacies, that they</p> <p>22 were actually dispensed prescriptions.</p> <p>23 Q And when you say --</p> <p>24 A For the at-issue drugs in the at-issue</p> <p>25 time periods by the at-issue manufacturers. Again,</p>

<p style="text-align: right;">Page 38</p> <p>1 the retail pharmacies provided this information to</p> <p>2 us. They are sitting on much more information that</p> <p>3 was not provided to us. They did this cut of the</p> <p>4 data, and we had to live with the cut that they</p> <p>5 were -- they provided to us.</p> <p>6 Q When you say that was all that was</p> <p>7 represented to us, who is the "us" in that sentence?</p> <p>8 A Myself and my staff.</p> <p>9 MS. WHITELEY: Objection. Counsel, to</p> <p>10 the extent that you're asking for</p> <p>11 attorney/client privileged information and work</p> <p>12 product information, we're objecting to that.</p> <p>13 The witness may answer.</p> <p>14 THE WITNESS: Thank you.</p> <p>15 Myself and my staff.</p> <p>16 BY MS. KAPKE:</p> <p>17 Q So who made that representation to</p> <p>18 you? Was that -- and I -- I don't want to get into</p> <p>19 privileged communication, but it is an assumption</p> <p>20 under proving your opinion. So I want to confirm</p> <p>21 whether that's an assumption that you got from</p> <p>22 plaintiffs' counsel or if there's some document that</p> <p>23 you read from -- from the retail pharmacy defendants</p> <p>24 that confirms that.</p> <p>25 A I think we have already established</p>	<p style="text-align: right;">Page 40</p> <p>1 the date, timestamp of when that prescription</p> <p>2 is actually dispensed to the consumer, there is</p> <p>3 the dispensing fee. And -- and many other --</p> <p>4 there's the name of the prescribing physician</p> <p>5 and their -- usually their national prescriber</p> <p>6 ID number, and on and on.</p> <p>7 We were not provided that data, myself</p> <p>8 and my staff.</p> <p>9 The -- my understanding is that the</p> <p>10 retail pharmacies provided a very limited view</p> <p>11 of the data that they have access to, that was</p> <p>12 related, as we have already discussed, to</p> <p>13 the -- the manufacturer name; the product name,</p> <p>14 including the NDC code, the month, year and</p> <p>15 state, and whether -- and whether and how much</p> <p>16 the consumer paid out-of-pocket as a function</p> <p>17 of co-insurance or co-payment analysis.</p> <p>18 That's all we were provided out of</p> <p>19 this universe of much more data that they must</p> <p>20 collect for every single dispensed prescription</p> <p>21 in America.</p> <p>22 BY MS. KAPKE:</p> <p>23 Q Were you aware of whether the retailer</p> <p>24 claims data included information from PBMs?</p> <p>25 A What do you mean by that?</p>
<p style="text-align: right;">Page 39</p> <p>1 this, ma'am.</p> <p>2 Q I -- then -- then answer the question</p> <p>3 again. I don't -- I don't know the answer.</p> <p>4 A I don't understand your question that</p> <p>5 you just asked, frankly. It was a multiple,</p> <p>6 compound question.</p> <p>7 Q Okay. Did plaintiffs' counsel tell</p> <p>8 you to assume that the retailer claims data only</p> <p>9 included prescriptions that were actually filled at</p> <p>10 a defendant pharmacy?</p> <p>11 MS. WHITELEY: Same objection.</p> <p>12 You may answer.</p> <p>13 THE WITNESS: I don't understand your</p> <p>14 question, ma'am. I -- I know a lot about the</p> <p>15 data that retail pharmacies generate when they</p> <p>16 are dispensing a prescription. There is a ton</p> <p>17 of data that is generated, as I have already</p> <p>18 alluded to.</p> <p>19 There's the name of the consumer.</p> <p>20 There's their address. There's their telephone</p> <p>21 number. There is whether or not that</p> <p>22 prescription is insured and by whom, by what</p> <p>23 insurer. Then there is the claim amount, and</p> <p>24 then there is the paid amount.</p> <p>25 And there's other information as well;</p>	<p style="text-align: right;">Page 41</p> <p>1 Q I'm asking if, to your knowledge, the</p> <p>2 retailer claims data includes PBM customer data?</p> <p>3 A What is PBM customer data? Who is the</p> <p>4 customer -- I mean, the consumer -- the patient is</p> <p>5 the customer, right? They're the person who's</p> <p>6 dispensed the prescription. They're the customer of</p> <p>7 the pharmacy. What is PBM customer data?</p> <p>8 Q Do you understand that there</p> <p>9 are -- I'll -- I'll ask a different question.</p> <p>10 Did the data you were provided include</p> <p>11 prescriptions dispensed from pharmacies other than</p> <p>12 the pharmacies who are defendants in this case?</p> <p>13 A I'm not sure I'm following your</p> <p>14 question. I'm sorry.</p> <p>15 Q So the retailer claims data has --</p> <p>16 A Right.</p> <p>17 Q -- has data from -- that -- that</p> <p>18 reflects prescription fills at those defendant</p> <p>19 pharmacies, CVS, Rite Aid, other -- other defendant</p> <p>20 pharmacies. Are you with me there?</p> <p>21 A I don't know -- I don't know what you</p> <p>22 mean by "other defendant pharmacies." The data that</p> <p>23 I have are the -- are the retailer pharmacies that</p> <p>24 we reviewed when we first started talking. They're</p> <p>25 listed in my Attachment B, right? We established</p>

<p style="text-align: right;">Page 42</p> <p>1 that those were the ones that were provided to me.</p> <p>2 Q Right.</p> <p>3 A I'm happy to go through them again.</p> <p>4 So there's Albertsons, CVS, Kroger, Optum,</p> <p>5 Express Scripts, Walgreens and Walmart.</p> <p>6 Q Correct. Does the data in -- in the</p> <p>7 retailer claims data contain information about</p> <p>8 prescriptions dispensed from pharmacies who are not</p> <p>9 defendants in this case?</p> <p>10 A Are you asking me whether Albertsons</p> <p>11 gave me data from non-Albertsons pharmacies?</p> <p>12 Q In general, yes.</p> <p>13 A I don't understand the question. I</p> <p>14 don't understand -- I don't understand how</p> <p>15 Albertsons would have data from CVS or CVS would</p> <p>16 have data from Walmart or Walgreens.</p> <p>17 Q Okay.</p> <p>18 A I -- I mean, you know, I -- I don't</p> <p>19 understand that. I'm sorry.</p> <p>20 Q Okay. So --</p> <p>21 A These are massive public companies. I</p> <p>22 don't see how they would have access to other public</p> <p>23 companies' dispensing data at the level of</p> <p>24 aggregation that we were provided.</p> <p>25 Q Are you aware of the concept in the</p>	<p style="text-align: right;">Page 44</p> <p>1 provided to me.</p> <p>2 Q I want to move now to how you used</p> <p>3 Conti Exhibit 7, what you did with it.</p> <p>4 Am I correct that the retailer damages</p> <p>5 output file is the basis of the calculations that</p> <p>6 are listed for the retail pharmacy defendants in</p> <p>7 Attachments G, H and I of your report?</p> <p>8 A It's the output file that corresponds</p> <p>9 to the exhibits.</p> <p>10 Q Okay. So let's -- let's go through</p> <p>11 the --</p> <p>12 A It's not -- it's not the native data,</p> <p>13 right?</p> <p>14 Q Correct.</p> <p>15 A And it's not the -- it's not the --</p> <p>16 it's aggregated.</p> <p>17 Q Correct.</p> <p>18 Okay. So let's -- I want to go</p> <p>19 through Attachment -- Attachments G, H and I. So</p> <p>20 let's take a look at G.1.</p> <p>21 A G.1.</p> <p>22 Q This the state grouping file --</p> <p>23 A Just one second. Just one second,</p> <p>24 please. I'm not there yet. Okay. G.1, okay.</p> <p>25 Q That's the state grouping file</p>
<p style="text-align: right;">Page 43</p> <p>1 pharmaceutical industry of a data sale from one</p> <p>2 pharmacy to another?</p> <p>3 A No.</p> <p>4 Q Did you consider whether any of the</p> <p>5 retailer claims data included within it included</p> <p>6 prescription fills from non-defendant pharmacies</p> <p>7 that subsequently sold their consumer data to one of</p> <p>8 the defendant pharmacies?</p> <p>9 A I -- I'm sorry. They may do that for</p> <p>10 intelligence purposes, but I am not aware that that</p> <p>11 is the data that was provided.</p> <p>12 We were provided transaction data at</p> <p>13 the pharmacy level. Each pharmacy has a pharmacy</p> <p>14 identifier. It's standard. It's actually required</p> <p>15 to be reported and kept by the regulators. And so</p> <p>16 I'm assuming that the data that was provided, at</p> <p>17 least the native format of the data, has that</p> <p>18 pharmacy ID.</p> <p>19 But, again, if the retail pharmacies</p> <p>20 that -- were the ones who provided the data in the</p> <p>21 form that they gave it to me, if they did not -- if</p> <p>22 they mistakenly did not include their own pharmacy</p> <p>23 ID or accurately counted their own pharmacy ID in</p> <p>24 the data they had, that's upstream of -- there's no</p> <p>25 way that I could check that in the data that was</p>	<p style="text-align: right;">Page 45</p> <p>1 provided to you by plaintiffs' counsel, correct?</p> <p>2 THE COURT REPORTER: I'm sorry, was</p> <p>3 there an answer?</p> <p>4 THE WITNESS: I said correct.</p> <p>5 BY MS. KAPKE:</p> <p>6 Q And you have no opinion on whether</p> <p>7 these groupings are accurate, correct?</p> <p>8 A What do you mean by "accurate"?</p> <p>9 MR. HONIK: Object to form and to the</p> <p>10 extent it calls for a legal conclusion.</p> <p>11 Good morning, Kara. I apologize for</p> <p>12 joining late.</p> <p>13 MS. KAPKE: No -- no worries.</p> <p>14 BY MS. KAPKE:</p> <p>15 Q And I just want to make sure that</p> <p>16 these groupings aren't a reflection of a legal</p> <p>17 conclusion on your part. They're just information</p> <p>18 and assumptions given to you by plaintiffs' counsel,</p> <p>19 correct?</p> <p>20 MR. HONIK: Thank you.</p> <p>21 THE WITNESS: So in the notes of</p> <p>22 Attachment G-1 -- please scroll down to the</p> <p>23 next page. It states very clearly, "Retailer</p> <p>24 Implied Warranty Table, provided by counsel."</p> <p>25</p>

<p style="text-align: right;">Page 46</p> <p>1 BY MS. KAPKE:</p> <p>2 Q Right. I -- I understand that it was</p> <p>3 provided to you by counsel. And I just want to</p> <p>4 confirm that that also means that these groupings</p> <p>5 are not a reflection of any opinions that you have</p> <p>6 regarding liability or state laws or legal</p> <p>7 ramifications?</p> <p>8 MR. HONIK: Object to form.</p> <p>9 THE WITNESS: I'm an economist and</p> <p>10 expert on the pharmaceutical industry. I'm not</p> <p>11 a lawyer. I don't have an opinion about these</p> <p>12 groupings. They were provided to me by</p> <p>13 counsel. I think we've established that.</p> <p>14 BY MS. KAPKE:</p> <p>15 Q Okay. And the same is true for</p> <p>16 Attachment H.1 and I.1 as well?</p> <p>17 A Let's look. So if you go to the next</p> <p>18 page in H.1, same thing noted, "Retailer Consumer</p> <p>19 Protection Act Claims Table, provided by counsel."</p> <p>20 Q So the answer to my question is yes,</p> <p>21 you don't have an opinion about these groupings --</p> <p>22 A Actually, you didn't ask me a</p> <p>23 question. Again, this information was provided to</p> <p>24 me by counsel. I don't have a legal opinion. I'm</p> <p>25 not a lawyer.</p>	<p style="text-align: right;">Page 48</p> <p>1 It's -- it's explained. So in paragraphs 63 and 64,</p> <p>2 I explain what I did for the defendant retailers for</p> <p>3 unjust enrichment. I list, "Retailers profited from</p> <p>4 the sale of at-issue valsartan products to consumers</p> <p>5 at the point of sale. Profits are defined as</p> <p>6 revenues minus cost for each at-issue valsartan</p> <p>7 product sold by the defendant retailers from</p> <p>8 January 1st until the at-issue valsartan products</p> <p>9 were recalled in 2018 and 2019 for being adulterated</p> <p>10 and misbranded."</p> <p>11 I then have, again, a footnote where</p> <p>12 we have established which of the products at-issue</p> <p>13 and at what time periods. All I did was take the</p> <p>14 information that was provided to me by the at-issue</p> <p>15 retailers for the relevant time periods, the</p> <p>16 relevant manufacturers and the relevant product</p> <p>17 categories, and matched them with the states</p> <p>18 relevant for the unjust enrichment damages and</p> <p>19 summed them up.</p> <p>20 I did the exact same thing for the</p> <p>21 liability claims, and I think that is listed and</p> <p>22 explained in my report, in the preceding section, in</p> <p>23 Paragraphs 60, 61 and 62.</p> <p>24 Q And what I'm trying to -- to</p> <p>25 understand and make sure that I -- I follow, is what</p>
<p style="text-align: right;">Page 47</p> <p>1 Q Okay. So --</p> <p>2 A And then you asked me for another</p> <p>3 attachment, H.1. And then which other table?</p> <p>4 Q I.1.</p> <p>5 A I.1. So I.1, again, has the same</p> <p>6 note, "Retailer Unjust Enrichment Table, provided by</p> <p>7 counsel."</p> <p>8 Q So the same caveat as you made before,</p> <p>9 that you don't have a legal opinion, you're not a</p> <p>10 lawyer, would also apply to I.1, correct?</p> <p>11 A It's not a caveat. You asked me a</p> <p>12 question, do I have a legal opinion. And I'm saying</p> <p>13 I'm an economist. I'm not a lawyer. I don't have</p> <p>14 an opinion on liability other than -- or the</p> <p>15 inclusion, other than what was provided to me by</p> <p>16 counsel to calculate.</p> <p>17 Q Right. Okay. So what I want to do is</p> <p>18 make sure that I understand how you derived the</p> <p>19 remainder of the Attachments to G, H and I. And</p> <p>20 what I think you did to create the remainder of</p> <p>21 those attachments is simply sum up the totals for</p> <p>22 the relevant state and retailer found within</p> <p>23 Conti Exhibit 7 where called for, according to</p> <p>24 attachment G.1, H.1 or I.1.; is that correct?</p> <p>25 A Let's go back to my report and assess.</p>	<p style="text-align: right;">Page 49</p> <p>1 you're doing is you're basically sorting and</p> <p>2 filtering on the Excel spreadsheet that is</p> <p>3 Conti Exhibit 7, correct?</p> <p>4 MR. HONIK: Object to the form.</p> <p>5 THE WITNESS: Okay. So it's probably</p> <p>6 easiest just to go back to the paragraph where</p> <p>7 I explained the procedure again. It's in</p> <p>8 paragraph 78 under, "Defendant Retailer</p> <p>9 Liability Damages and Unjust Enrichment</p> <p>10 Damages."</p> <p>11 So in the paragraph, I explain what we</p> <p>12 did. To calculate defendant retailer theory of</p> <p>13 liability damages and unjust enrichment</p> <p>14 damages, I rely upon the defendant retailer</p> <p>15 pharmacy claims data. These claims datasets</p> <p>16 have been limited to the consumer paid amounts.</p> <p>17 That is, they exclude the all third-party payor</p> <p>18 amounts, and thus represent the revenues</p> <p>19 described in the section previous. I already</p> <p>20 provided that information.</p> <p>21 The consumer paid amounts in the</p> <p>22 defendant retailer pharmacy claim datasets</p> <p>23 provided to me do not include data on</p> <p>24 dispensing fees, nor any of the other</p> <p>25 information that I already discussed as</p>

<p style="text-align: right;">Page 50</p> <p>1 potentially relevant but not -- again, that</p> <p>2 they have but was not provided to me.</p> <p>3 Therefore, I don't subtract page</p> <p>4 dispensing fees to offset the cost of the</p> <p>5 retailer pharmacies dispensing these products</p> <p>6 to consumers. This offset has already been</p> <p>7 done by the defendant retailer. For each set</p> <p>8 of defendant retailer pharmacy claims, I limit</p> <p>9 the claims to the at-issue valsartan product</p> <p>10 NDC codes found in the IQVIA dataset and</p> <p>11 provided to me by counsel.</p> <p>12 I then sum the total consumer paid</p> <p>13 amounts by product, defendant retailer and</p> <p>14 state. When there is a difference for retail</p> <p>15 pharmacy claims, I use the state in which the</p> <p>16 retailer pharmacy was located. For mail order</p> <p>17 pharmacy claims, I use the state where the</p> <p>18 prescription was mailed.</p> <p>19 I then -- and then all I did was match</p> <p>20 that to the states at issue for the specific</p> <p>21 theory of liability, whether it be liability 1,</p> <p>22 2 or unjust enrichment claims. And all they</p> <p>23 are varying by is the states that are included</p> <p>24 in that. It's exactly the same procedure.</p> <p>25</p>	<p style="text-align: right;">Page 52</p> <p>1 data that might be -- the data that was -- that</p> <p>2 underlies each one of those steps.</p> <p>3 Q Is there anything that you just talked</p> <p>4 about with manufacturer NDC groupings, or the</p> <p>5 instructions in your report, that is not contained</p> <p>6 already in Exhibit 7?</p> <p>7 MR. HONIK: Object to form.</p> <p>8 THE WITNESS: I'm sorry. What's</p> <p>9 Exhibit 7?</p> <p>10 BY MS. KAPKE:</p> <p>11 Q The output file.</p> <p>12 A There's -- that data is -- there's</p> <p>13 underlying data underneath that that you would</p> <p>14 probably need.</p> <p>15 Q What data would you need underlying</p> <p>16 the output file to create new Attachments G, H and I</p> <p>17 if you were given new states at issue?</p> <p>18 A You would need the data that you, the</p> <p>19 retailers, provided to me.</p> <p>20 Q Why? Why isn't that already addressed</p> <p>21 in your output file?</p> <p>22 MR. HONIK: Object to form.</p> <p>23 THE WITNESS: I'm not following your</p> <p>24 question. I'm sorry.</p> <p>25</p>
<p style="text-align: right;">Page 51</p> <p>1 Q And I -- I appreciate that you're</p> <p>2 trying to be helpful, but you don't need to -- to</p> <p>3 read the report. What -- what I'm -- what I'm</p> <p>4 trying to -- to understand is if the state groupings</p> <p>5 were to change, if plaintiffs gave you a different</p> <p>6 version of G.1, H.1 or I.1 with different state</p> <p>7 groupings, would we need your expertise to create a</p> <p>8 subsequent version of attachments G, H and I, or</p> <p>9 could we do that based on what you already gave us</p> <p>10 with the Conti Exhibit 7, the output file, and</p> <p>11 simply sort, filter, and subtotal to create new</p> <p>12 Attachments G, H and I?</p> <p>13 A So my method is flexible to</p> <p>14 accommodate other -- other assumptions, that</p> <p>15 inclusion or exclusions of states. I think you</p> <p>16 would have to go back to the data that was provided</p> <p>17 to me by the retailer pharmacies and the</p> <p>18 manufacturer NDC groupings where we picked up --</p> <p>19 remember, I mentioned we picked up repackager and --</p> <p>20 and private label drugs that have recast or</p> <p>21 relabeled NDC codes in order to make that</p> <p>22 calculation.</p> <p>23 But any trained analyst could -- could</p> <p>24 do that calculation, following the -- following the</p> <p>25 instructions that are provided in my report and the</p>	<p style="text-align: right;">Page 53</p> <p>1 BY MS. KAPKE:</p> <p>2 Q What I'm trying to understand is</p> <p>3 say -- say we took out -- you know, we changed two</p> <p>4 states in Attachment G, G.1. Why can't I go to</p> <p>5 the -- the output file and just do a sort and filter</p> <p>6 and then create new numbers? What -- what data are</p> <p>7 you using?</p> <p>8 I don't think you're using anything.</p> <p>9 I think it's a simple sort and filter. And so</p> <p>10 that's what I'm trying to understand. Is there</p> <p>11 something you are doing or can -- can anyone do --</p> <p>12 do it once you have the output file?</p> <p>13 MR. HONIK: Object to form, asked and</p> <p>14 answered.</p> <p>15 THE WITNESS: So, Ms. Kapke, I don't</p> <p>16 feel comfortable with the idea that you just</p> <p>17 sort and filter. That's not what good data</p> <p>18 analysts do. They build that -- if you're</p> <p>19 going to redo the calculations to -- based</p> <p>20 on -- on other assumptions, good data practices</p> <p>21 is to go back to the original dataset, ensure</p> <p>22 the data is complete, doesn't contain any</p> <p>23 mistakes, and then go through the steps again</p> <p>24 to get to the calculation that's at issue.</p> <p>25 I told you that the steps that we went</p>

<p style="text-align: right;">Page 54</p> <p>1 through are listed in my report. They're very</p> <p>2 clear, and they're very simple. And so any</p> <p>3 analyst, who is well trained, should be able to</p> <p>4 follow the steps if the states change, if the</p> <p>5 NDC codes change, if there are additional</p> <p>6 calculations that need to get done.</p> <p>7 I would never tell, even, like, my</p> <p>8 undergrads where the IT stats are to, to just</p> <p>9 sort and filter to get the right -- to get a</p> <p>10 different data. That is bad data management</p> <p>11 practice. You go back to the original data and</p> <p>12 you would calculate it.</p> <p>13 BY MS. KAPKE:</p> <p>14 Q Okay. I'm going to move on to --</p> <p>15 THE WITNESS: So actually, I'd like to</p> <p>16 take a break, please. So can I have</p> <p>17 five minutes?</p> <p>18 MS. KAPKE: Sure.</p> <p>19 MR. HONIK: Let's resume at 10:20.</p> <p>20 THE VIDEOGRAPHER: The time is 10:14.</p> <p>21 This ends Media Unit Number 1. We're off the</p> <p>22 record.</p> <p>23 (Whereupon, a short break was taken.)</p> <p>24 THE VIDEOGRAPHER: The time is 10:22.</p> <p>25 This begins Media Unit Number 2. We're back on</p>	<p style="text-align: right;">Page 56</p> <p>1 And I -- I think I get it, but I'm --</p> <p>2 I want to make sure that I do. So I want to use an</p> <p>3 example to make sure that I understand. And -- and</p> <p>4 if I get my example wrong, you can correct me.</p> <p>5 So do you recall --</p> <p>6 A Wait. Hold on. I just want to make</p> <p>7 sure that I understand. So are we focused on the</p> <p>8 retailer damages, or are we focused on Table 1 where</p> <p>9 the manufacturer damages is?</p> <p>10 Q I'm going to give you an example</p> <p>11 that's focused on the retailer examples.</p> <p>12 A Okay. Table 2 and 3, correct?</p> <p>13 Q Yeah. I'm looking specifically at --</p> <p>14 the attachment is what I want to look at. So what I</p> <p>15 want to look at is -- let's say consumer protection</p> <p>16 damages for CVS for Arizona. So that's in</p> <p>17 Table H.2.</p> <p>18 A Wait. Hold on. So -- so I'm on</p> <p>19 Table 2 where we talk about deduplication</p> <p>20 and -- okay. So --</p> <p>21 Q I want you to go to Attachment H.2.</p> <p>22 A H.2, okay.</p> <p>23 Q And you've got a calculation there for</p> <p>24 consumer protection damages for CVS for Arizona -- I</p> <p>25 just picked a state at random -- for [REDACTED]</p>
<p style="text-align: right;">Page 55</p> <p>1 the record.</p> <p>2 BY MS. KAPKE:</p> <p>3 Q Dr. Conti, during the break, did you</p> <p>4 talk to any of your staff?</p> <p>5 A No.</p> <p>6 Q Okay. So I'm going to ask you about</p> <p>7 what you were saying regarding deduplication of</p> <p>8 damages in your report. I think I understand, but I</p> <p>9 want to use an example to make sure that I'm -- I'm</p> <p>10 following what you're saying. So let's look --</p> <p>11 A Can you -- can you direct me -- can</p> <p>12 you direct me to where in my report you're focused</p> <p>13 on?</p> <p>14 Q Sure.</p> <p>15 So in your summary of damages in</p> <p>16 paragraph 79, you say, "I present deduplicated</p> <p>17 aggregate damages." And I'm just focused on the</p> <p>18 word "deduplicated."</p> <p>19 A I don't see the -- that in paragraph</p> <p>20 79. Hold on. You mean in reference to Table 1 and</p> <p>21 then in reference to Table 2 and 3?</p> <p>22 Q Yes.</p> <p>23 A There are two footnotes and one</p> <p>24 paragraph where deduplication is referred to.</p> <p>25 Q Right. I understand.</p>	<p style="text-align: right;">Page 57</p> <p>1 right?</p> <p>2 A I see that.</p> <p>3 Q Okay. And -- and that is the sum</p> <p>4 total, equal to the full patient paid amount, for</p> <p>5 the at-issue valsartan for the relevant time period</p> <p>6 as reflected in the retailer claims data produced by</p> <p>7 CVS, correct?</p> <p>8 A Under this period of damage, correct.</p> <p>9 Q Okay.</p> <p>10 A And for all of the included --</p> <p>11 THE COURT REPORTER: I'm sorry?</p> <p>12 THE WITNESS: And for all of the</p> <p>13 included NDC codes and manufacturers at-issue</p> <p>14 in the relevant time period.</p> <p>15 BY MS. KAPKE:</p> <p>16 Q Got it. We're on the same page here.</p> <p>17 This shouldn't be controversial, I don't think. I</p> <p>18 just want to make sure that I understand.</p> <p>19 A I just want to -- I just want to make</p> <p>20 sure that I understand what you're saying because</p> <p>21 there's clearly been some mismatch in the language</p> <p>22 that you're using as opposed to what I understand is</p> <p>23 this data or these analyses.</p> <p>24 Q And please. Please always --</p> <p>25 that's -- that's one of the first things that</p>

<p style="text-align: right;">Page 58</p> <p>1 Mr. Goldberg told you yesterday, was if you don't</p> <p>2 understand a question, let us know. And -- and we</p> <p>3 definitely want that.</p> <p>4 So let's go to Attachment I.2, which</p> <p>5 is the unjust enrichment calculations. And the</p> <p>6 total is the exact same for CVS for Arizona on</p> <p>7 unjust enrichment calculations, correct?</p> <p>8 A For Arizona, yes.</p> <p>9 Q So when you talk about total damages</p> <p>10 across defendant manufacturers and retailers not</p> <p>11 being intended to be summed, you're not intending</p> <p>12 for anyone to sum both consumer protection damages</p> <p>13 and unjust enrichment damages for Arizona or CVS; is</p> <p>14 that correct?</p> <p>15 MR. HONIK: Note my objection to the</p> <p>16 extent it calls for a legal conclusion.</p> <p>17 But you may answer.</p> <p>18 THE WITNESS: So, the -- the -- that's</p> <p>19 why I referred to Table 2 and Table 3, if we</p> <p>20 could go back and explain the deduplication.</p> <p>21 Right. So the liability damages per state and</p> <p>22 per manufacturer are deduplicated.</p> <p>23 So what I mean by that is, if the</p> <p>24 liability damages were calculated for one</p> <p>25 state, let's just say Arizona, in one theory of</p>	<p style="text-align: right;">Page 60</p> <p>1 conclusion.</p> <p>2 You may answer.</p> <p>3 THE WITNESS: Thank you.</p> <p>4 Allocation and apportionment is</p> <p>5 outside of the scope of my report.</p> <p>6 BY MS. KAPKE:</p> <p>7 Q You would agree that they reflect the</p> <p>8 same -- for a particular state and particular</p> <p>9 manufacturer, they represent the same data which is</p> <p>10 the full patient paid amount, correct?</p> <p>11 MR. HONIK: Object to the form.</p> <p>12 THE WITNESS: I disagree with that</p> <p>13 characterization.</p> <p>14 BY MS. KAPKE:</p> <p>15 Q Correct it then, please.</p> <p>16 MR. HONIK: Object to form.</p> <p>17 You can answer.</p> <p>18 THE WITNESS: Okay. So let's go back</p> <p>19 to the basis of liability versus unjust</p> <p>20 enrichment.</p> <p>21 Liability is related to what was paid</p> <p>22 at the point of sale. In this case, by the --</p> <p>23 by the consumer and TPP, if we're taking this</p> <p>24 from a theoretical perspective. And so the</p> <p>25 full amount of retailer liability is the -- the</p>
<p style="text-align: right;">Page 59</p> <p>1 liability, and then calculated for another --</p> <p>2 for exactly the same state, for another theory</p> <p>3 of liability for retailers, they were only</p> <p>4 counted once in Table 2.</p> <p>5 The unjust enrichment damages are a</p> <p>6 separate calculation for every relevant state</p> <p>7 manufacturer NDC code finding. So you're</p> <p>8 actually comparing apples to oranges. The</p> <p>9 unjust enrichment tables are their own thing.</p> <p>10 And they are listed under Table 3.</p> <p>11 Deduplication is referring to the liability</p> <p>12 claims, and they are listed in Table 2. That's</p> <p>13 why the deduplication note is referencing</p> <p>14 Table 2, not Table 3.</p> <p>15 BY MS. KAPKE:</p> <p>16 Q Are you giving an opinion that a</p> <p>17 consumer plaintiff would be entitled to unjust</p> <p>18 enrichment and liability damages from a retail</p> <p>19 pharmacy defendant for a particular state?</p> <p>20 THE COURT REPORTER: I'm sorry. Can</p> <p>21 I -- can I hear the end of the question,</p> <p>22 please?</p> <p>23 MS. KAPKE: For a particular state.</p> <p>24 MR. HONIK: Note my objection to the</p> <p>25 extent it requires a legal expert opinion or</p>	<p style="text-align: right;">Page 61</p> <p>1 full amount that -- that was paid by the</p> <p>2 consumer and by the third-party payor at the</p> <p>3 point of sale, and does not include offsets</p> <p>4 such as rebates or discounts that might have</p> <p>5 been applied later.</p> <p>6 Whereas unjust enrichment, if you go</p> <p>7 to Section C of my report, paragraph 64,</p> <p>8 entails understanding what the retailer profits</p> <p>9 from that sale are. And that would include,</p> <p>10 again, in theory, what the customer paid, what</p> <p>11 the third-party payor paid, inclusive, minus</p> <p>12 the retailer costs.</p> <p>13 Now, those costs, the retailers have</p> <p>14 already taken out the dispensing fee, but one</p> <p>15 can imagine there would be potentially other</p> <p>16 costs of dispensing those specific products</p> <p>17 that may be related to the point of sale, and</p> <p>18 might include other offsets that could have</p> <p>19 occurred.</p> <p>20 I discussed that in Footnote 84 where</p> <p>21 I say, "When calculating profits, the other</p> <p>22 offsets may be removed from gross profit should</p> <p>23 the jury or court find these to be reasonable</p> <p>24 deductions." That is relevant to unjust</p> <p>25 enrichment. It's not relevant to liability.</p>

<p style="text-align: right;">Page 62</p> <p>1 BY MS. KAPKE:</p> <p>2 Q In terms of the actual calculation in</p> <p>3 Attachment I --</p> <p>4 A Which -- which attachment -- which</p> <p>5 exhibit?</p> <p>6 Q I.</p> <p>7 A Right, which exhibit?</p> <p>8 Q Your report, Exhibit 5.</p> <p>9 MR. HONIK: I think there are multiple</p> <p>10 Is.</p> <p>11 THE WITNESS: Yeah. There are</p> <p>12 multiple Is. There are -- there are -- are</p> <p>13 multiple -- there's -- I think there are five</p> <p>14 Is.</p> <p>15 BY MS. KAPKE:</p> <p>16 Q Okay. We can pick any one of them,</p> <p>17 I.2, I.3, I --</p> <p>18 A I can't hear you. I'm sorry.</p> <p>19 Q We can just go to I.2.</p> <p>20 A Okay, I.2. Okay. That's the unjust</p> <p>21 enrichment table.</p> <p>22 Q Correct.</p> <p>23 A Right --</p> <p>24 Q It's --</p> <p>25 A Right. Which was -- which -- right?</p>	<p style="text-align: right;">Page 64</p> <p>1 there might be -- so this is the revenue paid for</p> <p>2 this specific claim, aggregated over multiple drugs,</p> <p>3 multiple --</p> <p>4 THE COURT REPORTER: Multiple what?</p> <p>5 THE WITNESS: Manufacturers, multiple</p> <p>6 time periods.</p> <p>7 But there might be additional costs</p> <p>8 that CVS incurred in dispensing that product in</p> <p>9 a particular time period. All I have is what</p> <p>10 was paid. But from a theoretical perspective,</p> <p>11 unjust enrichment should account for the cost</p> <p>12 of dispensing that prescription, which might be</p> <p>13 captured by the dispensing fee, but might have</p> <p>14 additional costs on top of it. That's very</p> <p>15 different than the theory of liability.</p> <p>16 BY MS. KAPKE:</p> <p>17 Q Putting aside this theoretical</p> <p>18 perspective, in terms of the actual generation of</p> <p>19 Attachment I.2, compared to the actual generation of</p> <p>20 Attachment H.2 --</p> <p>21 A Wait. Hold on. Let's go back to H.2</p> <p>22 because I'm not sure. I just want to follow along</p> <p>23 with you.</p> <p>24 Okay. So I.2 is unjust enrichment for</p> <p>25 CVS, and H.2 is liability claim for CVS. Okay.</p>
<p style="text-align: right;">Page 63</p> <p>1 Which is enumerated in sum in Table 3.</p> <p>2 Q Correct.</p> <p>3 In terms of the actual calculations</p> <p>4 done in Attachment I.2 --</p> <p>5 A For CVS?</p> <p>6 Q For CVS.</p> <p>7 A Uh-huh.</p> <p>8 Q It is equal to the full patient paid</p> <p>9 amount, correct?</p> <p>10 A Well, it's equal to the amount of</p> <p>11 co-insurance and co-payments. There might be other</p> <p>12 payments that were made, including a dispense fee.</p> <p>13 There might be other payments that are made or other</p> <p>14 offsets that were made. We just have what we were</p> <p>15 provided by CVS, which is the consumer co-insurance</p> <p>16 and co-payment amounts.</p> <p>17 Q If you look at the notes, if you --</p> <p>18 you reference it being equal to the full patient</p> <p>19 paid amount?</p> <p>20 A But, again, as I mentioned, there are</p> <p>21 other amounts which include the dispensing fee that</p> <p>22 consumers usually pay at the pharmacy counter.</p> <p>23 Those were taken out to arrive at these sums.</p> <p>24 And the point of unjust enrichment is</p> <p>25 that it's based on the profit that CVS made, so</p>	<p style="text-align: right;">Page 65</p> <p>1 Q So putting aside the theoretical</p> <p>2 perspective, the numbers generated in both H.2 and</p> <p>3 I.2 are both based on the CVS retail claims data</p> <p>4 equal to full patient paid amount?</p> <p>5 A That's correct.</p> <p>6 MR. HONIK: Object to form.</p> <p>7 BY MS. KAPKE:</p> <p>8 A So I mean, mechanically, they are the</p> <p>9 same, but theoretically, they are not the same. And</p> <p>10 so for my calculation, I only had the data that was</p> <p>11 provided to me. When -- when and if a jury finds</p> <p>12 there to be -- an award to be made, there's a</p> <p>13 different process that would go into consumers or</p> <p>14 third-party payors claiming the amount that they are</p> <p>15 owed.</p> <p>16 And that's where the theory matters</p> <p>17 because the liability amounts in the actual world</p> <p>18 are going to be related to the paid amounts.</p> <p>19 Whereas, the unjust enrichment claims would be paid</p> <p>20 amounts minus cost or revenues minus the cost of</p> <p>21 that prescription being dispensed, which might be --</p> <p>22 which might have a particular offset associated with</p> <p>23 it.</p> <p>24 Q I'm going to go back to Tables 1 and</p> <p>25 2.</p>

<p style="text-align: right;">Page 66</p> <p>1 A Okay. Do you mean 2 and 3?</p> <p>2 Q No, I actually mean 1 and 2. I want</p> <p>3 to understand the interplay between Table 1, the</p> <p>4 aggregate manufacturer group damages and Table 2,</p> <p>5 the aggregate retailer damages across liability</p> <p>6 theories of damages.</p> <p>7 By necessity, any damage you've</p> <p>8 calculated in Table 2 for a retail pharmacy</p> <p>9 defendant would already be included in the</p> <p>10 manufacturer defendant calculations in Table 1,</p> <p>11 correct?</p> <p>12 MR. HONIK: Object to form.</p> <p>13 You can answer.</p> <p>14 THE WITNESS: Are you asking me</p> <p>15 whether the IQVIA data that goes into the</p> <p>16 calculation for Table 1 would include or be</p> <p>17 inclusive of the retailer liability calculation</p> <p>18 in Table 2 for each manufacturer retailer?</p> <p>19 BY MS. KAPKE:</p> <p>20 Q Sure. You can answer that question.</p> <p>21 THE COURT REPORTER: I'm sorry?</p> <p>22 BY MS. KAPKE:</p> <p>23 Q Yeah. Please answer that question.</p> <p>24 A Yes, but not in entirety. Because,</p> <p>25 again, the retailers are only focused on the -- the</p>	<p style="text-align: right;">Page 68</p> <p>1 allocation determinations? And it's good to know</p> <p>2 that you don't.</p> <p>3 A I have already testified to that -- to</p> <p>4 that three times this morning.</p> <p>5 Q I appreciate that.</p> <p>6 But -- but let's engage in a</p> <p>7 hypothetical world where the manufacturers pay all</p> <p>8 of the damages. So we're not in a -- in a world</p> <p>9 where allocation needs to be made, because the</p> <p>10 manufacturers have paid everything in the "Consumer</p> <p>11 Damages" column of Table 1. If that's the</p> <p>12 hypothetical position that you assume, are there any</p> <p>13 damages left for the retail pharmacy defendants to</p> <p>14 pay?</p> <p>15 MR. HONIK: Note my -- excuse me --</p> <p>16 note my objection on a couple of bases.</p> <p>17 Number 1, in the statement that was in</p> <p>18 your question, Kara, that confirmed at least in</p> <p>19 your question, that Dr. Conti made no</p> <p>20 allocations, that's not correct. She didn't</p> <p>21 make legal allocations, but she made lots and</p> <p>22 lots of mathematical allocations, and she spent</p> <p>23 hours talking about that. That's number 1.</p> <p>24 MS. KAPKE: Sure.</p> <p>25 MR. HONIK: And number 2, I just want</p>
<p style="text-align: right;">Page 67</p> <p>1 retailer liability claims are only focused on</p> <p>2 consumers' co-insurance and co-payment amounts.</p> <p>3 Whereas, the manufacturer liability claims are</p> <p>4 related to total payments for the at-issue drugs in</p> <p>5 the at-issue time periods and the at-issue data.</p> <p>6 Q So suppose a manufacturer -- strike</p> <p>7 that.</p> <p>8 Suppose the manufacturers paid to</p> <p>9 consumers all of the damages in Table 1 under</p> <p>10 "Consumer Damages." That would mean the consumers</p> <p>11 were satisfied in full, correct? There'd be no</p> <p>12 damages left for the retail pharmacy defendants to</p> <p>13 pay?</p> <p>14 MR. HONIK: Object to the form and to</p> <p>15 the extent it calls for a legal conclusion</p> <p>16 regarding ultimate allocation.</p> <p>17 THE THE COURT REPORTER: Ultimate...</p> <p>18 MR. HONIK: Allocation.</p> <p>19 THE COURT REPORTER: Thank you.</p> <p>20 THE WITNESS: Again, allocation</p> <p>21 concerns are outside the scope of my analysis.</p> <p>22 BY MS. KAPKE:</p> <p>23 Q And I -- and I understand that. And</p> <p>24 actually that was going to be my next question.</p> <p>25 Do you ever -- you know, do you make</p>	<p style="text-align: right;">Page 69</p> <p>1 to preserve my ongoing objection that your</p> <p>2 question really requires a legal conclusion</p> <p>3 about what liability will yield in the way of</p> <p>4 an allocation as directed by a court or a</p> <p>5 jury's verdict or otherwise.</p> <p>6 With that, she can answer.</p> <p>7 THE WITNESS: Thank you.</p> <p>8 So this is your hypothetical, and</p> <p>9 these are your assumptions. They're not mine.</p> <p>10 And my understanding is that -- that</p> <p>11 those determinations are ones that will be</p> <p>12 answered by a court and a jury. They are --</p> <p>13 they are outside my purview as I've already</p> <p>14 testified.</p> <p>15 BY MS. KAPKE:</p> <p>16 Q Okay. I'm going to try to ask another</p> <p>17 hypothetical question to get at it -- to get at it a</p> <p>18 different way.</p> <p>19 Assume a world in which all of -- all</p> <p>20 that has occurred to date has occurred except the</p> <p>21 filing of the lawsuit. And Aurobindo and Hetero and</p> <p>22 Mylan and Teva and Torrent and ZHP paid to consumers</p> <p>23 the sum total of [REDACTED], whatever the number is</p> <p>24 on the bottom of that --</p> <p>25 MS. KAPKE: Which I should note, for</p>

<p style="text-align: right;">Page 70</p> <p>1 the record, that that's considered -- that</p> <p>2 number is considered a confidential number for</p> <p>3 purposes -- thank you for zooming in -- for</p> <p>4 purposes of the protective order. I'm going to</p> <p>5 start my question over.</p> <p>6 THE WITNESS: Thank you.</p> <p>7 BY MS. KAPKE:</p> <p>8 Q Yeah. Assume a world in which</p> <p>9 everything has occurred except for the filing of</p> <p>10 the -- of this lawsuit. And independent of a</p> <p>11 lawsuit, the manufacturers listed in Table 1 pay out</p> <p>12 to consumers the damages listed in column -- the</p> <p>13 column marked "Consumer Damages" in Table 1.</p> <p>14 So outside of the legal realm, in that</p> <p>15 instance, do the consumers have any damages left?</p> <p>16 MR. HONIK: Note my objection on the</p> <p>17 same basis as previously stated and insofar as</p> <p>18 this is an improper hypothetical and well</p> <p>19 beyond the scope of a health economist's</p> <p>20 opinion as expressed here. Finally, I would</p> <p>21 just add by way of objection that what you're</p> <p>22 really getting at is a kind of reallocation,</p> <p>23 not allocation. And I remind everyone that</p> <p>24 what Dr. Conti has done is to simply present a</p> <p>25 methodology for assessing damages, the</p>	<p style="text-align: right;">Page 72</p> <p>1 question. I'm sorry. Are we still in</p> <p>2 that -- this weird hypothetical world?</p> <p>3 BY MS. KAPKE:</p> <p>4 Q No.</p> <p>5 A I wasn't asked to calculate or do any</p> <p>6 analysis of?</p> <p>7 Q No. I'm asking a separate question.</p> <p>8 A Oh, okay.</p> <p>9 Q Does -- would the -- the consumer</p> <p>10 damages total represent a full refund of all the</p> <p>11 money that the consumer spent on the at-issue</p> <p>12 valsartan?</p> <p>13 MR. HONIK: Same objection as</p> <p>14 previously stated.</p> <p>15 THE WITNESS: A full refund? What do</p> <p>16 you mean by "a full refund"? I don't use that</p> <p>17 term in my report, so I would like you</p> <p>18 to -- I'd like you to define it for me.</p> <p>19 BY MS. KAPKE:</p> <p>20 Q Would it -- I'll -- I'll withdraw that</p> <p>21 question.</p> <p>22 What do the numbers in the "Consumer</p> <p>23 Damages" column of Table 1 represent?</p> <p>24 MR. HONIK: Objection, asked and</p> <p>25 answered.</p>
<p style="text-align: right;">Page 71</p> <p>1 allocation of which, at trial or otherwise, is</p> <p>2 outside the scope of the purview of her</p> <p>3 assignment.</p> <p>4 You may answer.</p> <p>5 THE WITNESS: I have no answer. I</p> <p>6 mean, I have no -- I'm not a lawyer, and I have</p> <p>7 no assessment of whether or not that payment --</p> <p>8 THE THE COURT REPORTER: That</p> <p>9 payment...</p> <p>10 THE WITNESS: That payment is --</p> <p>11 satisfies the claims or not. It's completely</p> <p>12 outside the scope of my assignment in this</p> <p>13 case.</p> <p>14 MR. HONIK: Are you making an offer,</p> <p>15 Kara?</p> <p>16 MS. KAPKE: Sorry. I was chewing ice.</p> <p>17 Oh, that was your attempt at being funny.</p> <p>18 Sorry, Ruben. I should have laughed.</p> <p>19 BY MS. KAPKE:</p> <p>20 Q Does Table 1, "Consumer Damages,"</p> <p>21 represent a full refund of all the consumers spent</p> <p>22 on the at-issue valsartan?</p> <p>23 MR. HONIK: Object to the form and for</p> <p>24 the reasons previously stated.</p> <p>25 THE WITNESS: I don't understand your</p>	<p style="text-align: right;">Page 73</p> <p>1 THE WITNESS: Let's go back to my</p> <p>2 explanation of how Table 1 was calculated.</p> <p>3 BY MS. KAPKE:</p> <p>4 Q You know what? I can withdraw that</p> <p>5 question. That's okay.</p> <p>6 A I'm happy to go -- I mean, I'm on</p> <p>7 paragraph 60. It's described as paragraph 60</p> <p>8 through 62.</p> <p>9 Q And that's fine. Ruben's right. You</p> <p>10 have -- you've answered that question.</p> <p>11 I -- I want to ask about -- it says</p> <p>12 right above Table 1, "Total damages across defendant</p> <p>13 manufacturers and retailers are not intended to be</p> <p>14 summed."</p> <p>15 Can you elaborate on what you mean by</p> <p>16 that?</p> <p>17 A I'm not there yet. Hold on.</p> <p>18 So, again, this is about the</p> <p>19 deduplication that we have been talking about for a</p> <p>20 while now. Let's start from the beginning of the</p> <p>21 paragraph. It's the -- it's the paragraph -- it's</p> <p>22 the previous page. Thank you.</p> <p>23 In paragraph 79, I explain, "The</p> <p>24 following tables present aggregate damages across</p> <p>25 all theories of liability. Details on aggregate</p>

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<p style="text-align: right;">Page 74</p> <p>1 damages for defendant manufacturers and retailers at 2 the group, subgroup and state level are provided in 3 the attachments in this declaration. In Table 1, I 4 present deduplicated aggregate damages across all 5 theories of liability for the defendant 6 manufacturers. In Table 2, I present -- "I present 7 deduplicated aggregate damages across all theories 8 of liability for the defendant retailers. In 9 Table 3, I present deduplicated aggregate unjust 10 enrichment damages for the defendant retailers. As 11 described in footnote 62 above, some claims fall 12 into multiple theories of liability. Therefore, 13 total damages across defendant manufacturers," full 14 stop, "and retailers are not intended to be summed." 15 What I mean by that is, the Table 1 16 damages are deduplicated. Table 2 damages, across 17 different theories of liability, are also 18 deduplicated. I also have footnotes, 72 and 73, for 19 Tables 1 and 2 that -- that make that clear as well. 20 Q Do you have an estimation of what 21 percentage of the pharmacy market is covered by the 22 pharmacy defendants in this case? 23 MR. HONIK: Object to form. 24 THE WITNESS: Well, some of the 25 largest pharmacies in America are listed in the</p>	<p style="text-align: right;">Page 76</p> <p>1 (Whereupon, a short break was taken.) 2 THE VIDEOGRAPHER: The time is 11:03. 3 We're back on the record. 4 BY MS. KAPKE: 5 Q Dr. Conti, during the last break, or 6 any breaks today, have you had any communications 7 with anyone? 8 MR. HONIK: Note my objection to the 9 extent it may reveal confidential and 10 privileged counsel communication. 11 But without waiver of the objection, 12 she may answer. 13 THE WITNESS: I have spoken to my 14 counsel. 15 BY MS. KAPKE: 16 Q During both breaks? 17 MR. HONIK: Same objection. 18 You may answer. 19 THE WITNESS: Yes. 20 BY MS. KAPKE: 21 Q Okay. Have you -- have you had any 22 communications with staff? 23 A You already asked me that question at 24 the last break, and I said no. So at this same 25 break -- at this next break, no, I did not have any</p>
<p style="text-align: right;">Page 75</p> <p>1 retailers table. CVS, Walgreens, Walmart are 2 absolutely enormous sellers of prescription 3 drugs in the U.S. market. 4 BY MS. KAPKE: 5 Q And do you have an estimate of -- of 6 what percentage that is? 7 A No. 8 THE COURT REPORTER: I'm sorry. 9 You're both talking on top of each other. 10 So I have, "Do you have an estimate of 11 what percentage that is" as a question. And I 12 have, "No" as an answer. 13 THE WITNESS: No. I said not off the 14 top of my head. 15 BY MS. KAPKE: 16 Q That's fine. 17 Okay. I want to -- let's go back to 18 the formulas in your report on paragraph 60 and 61. 19 A Are we changing topics? 20 Q Yeah. 21 A Okay. Great. I would like to take a 22 break then, please. 23 MS. KAPKE: Okay. 24 THE VIDEOGRAPHER: The time is 10:55. 25 We're going off the record.</p>	<p style="text-align: right;">Page 77</p> <p>1 communications with my staff. 2 Q Okay. Perfect. 3 So I have a couple of questions that, 4 again, I'm not really intending to be super 5 controversial. But I just want to make sure I 6 understand. 7 So let's go to your report. And 8 paragraph 60 and 61, you reference consumer class 9 expenditures by breaking down into full payments for 10 uninsured cash paying purchases on the one hand -- 11 THE COURT REPORTER: I'm sorry, Kara. 12 I'm sorry. I lost you. 13 THE WITNESS: Yeah. I -- I don't see 14 it either. 15 THE COURT REPORTER: "Consumer class 16 expenditure by breaking it down into full 17 payments for the uninsured"... 18 MS. KAPKE: Cash paying purchases on 19 one hand, and this is the formula. And co-pays 20 for insurance -- or for insured consumers. 21 THE WITNESS: I'm sorry. You -- hold 22 on. I just want to try to understand what 23 you're asking. So you referenced paragraph 60. 24 Where do you see that? Because I don't see it. 25</p>

20 (Pages 74 - 77)

<p style="text-align: right;">Page 78</p> <p>1 BY MS. KAPKE:</p> <p>2 Q Your formula.</p> <p>3 A In paragraph -- in paragraph 60 on</p> <p>4 Formula 1? It is not related -- it does not break</p> <p>5 down into different types of payor types.</p> <p>6 Q I'm looking at Formula 2 in</p> <p>7 paragraph 61.</p> <p>8 A Okay. So you said -- you directed me</p> <p>9 to paragraph 60 and 61. I'm just trying to follow.</p> <p>10 Q Okay. Here's my question. When you</p> <p>11 reference uninsured cash paying purchases, are you</p> <p>12 referring to anyone who did not have a co-pay, or</p> <p>13 are you referring to a subset of those who paid with</p> <p>14 physical cash?</p> <p>15 A I don't understand your question. I'm</p> <p>16 sorry.</p> <p>17 Q In other words, are you -- are you</p> <p>18 including in your formula uninsured patients who</p> <p>19 paid for valsartan with a credit card? Do</p> <p>20 you -- what do you mean by cash?</p> <p>21 A Okay. Cash is cash, right? So what I</p> <p>22 mean by this is they are paying out of pocket. The</p> <p>23 method of payment, whether it be literally a \$5 bill</p> <p>24 or using a credit card, from the industry's</p> <p>25 perspective, both of those types of payments, that</p>	<p style="text-align: right;">Page 80</p> <p>1 MR. HONIK: Object to form.</p> <p>2 You can answer.</p> <p>3 THE WITNESS: I'm not following. What</p> <p>4 are the three groups?</p> <p>5 BY MS. KAPKE:</p> <p>6 Q The insured, co-pay or co-insurance</p> <p>7 pay group purchasers?</p> <p>8 A Hold on. Those are two groups, not</p> <p>9 three.</p> <p>10 MR. HONIK: Yeah.</p> <p>11 BY MS. KAPKE:</p> <p>12 Q That's what I don't understand --</p> <p>13 THE COURT REPORTER: I can't take this</p> <p>14 down. I cannot do that. One at a time.</p> <p>15 MR. HONIK: Kara, respectfully, I</p> <p>16 think you misspoke. You said insured. I think</p> <p>17 you meant cash. It's cash, co-pay,</p> <p>18 co-insurance.</p> <p>19 BY MS. KAPKE:</p> <p>20 Q No. So I'm looking at the third --</p> <p>21 under where -- the third line there, it says, Qdt</p> <p>22 co-pay equals the quantity of product d purchased at</p> <p>23 time period t for, 1, insured, 2, co-pay or 3,</p> <p>24 co-insurance paying purchasers.</p> <p>25 I don't know and -- I don't know what</p>
<p style="text-align: right;">Page 79</p> <p>1 people are paying out of pocket, they are paying in</p> <p>2 cash.</p> <p>3 Q Okay. That's what I assumed. I need</p> <p>4 to check all of my assumptions, and that's what</p> <p>5 we're here to do here today.</p> <p>6 So for the uninsured cash paying</p> <p>7 purchases, the formula requires input of the full</p> <p>8 purchase price of the product. How is that</p> <p>9 determined for the uninsured cash paying purchaser?</p> <p>10 MR. HONIK: Objection, asked and</p> <p>11 answered.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: It's the full amount</p> <p>14 that they paid at the pharmacy counter for the</p> <p>15 at-issue drugs.</p> <p>16 BY MS. KAPKE:</p> <p>17 Q Okay. And then for the other part of</p> <p>18 the formula, you're looking at insured co-pay or</p> <p>19 co-insurance paying purchasers -- purchasers,</p> <p>20 correct?</p> <p>21 A Right. That's what it says here.</p> <p>22 Q Yes. Here -- here is my question: Is</p> <p>23 there a difference between insured co-pay or</p> <p>24 co-insurance paying purchasers? Is there some sort</p> <p>25 of delineation between those three groups?</p>	<p style="text-align: right;">Page 81</p> <p>1 you mean, if there is a distinction between those</p> <p>2 three words, insured, co-pay or co-insurance. Or do</p> <p>3 they all mean the same thing?</p> <p>4 A Are you asking me for the definition</p> <p>5 of insured, co-pay, co-insurance?</p> <p>6 Q I'm asking if there's a difference</p> <p>7 between those -- those three things.</p> <p>8 A Okay. There is a variable in the</p> <p>9 Xponent data that delineates or distinguishes</p> <p>10 between people who are paying cash -- they're</p> <p>11 uninsured for that specific prescription -- and</p> <p>12 people who are -- who are insured and still are</p> <p>13 required to pay a co-insurance or co-pay amount.</p> <p>14 So the first part of this last phrase,</p> <p>15 "insured or cash" in the previous tab under</p> <p>16 "quantity," delineates the distinction. Are these</p> <p>17 people cash paying, or are these people insured and</p> <p>18 paying a co-payment or a co-insurance? And the way</p> <p>19 that you can tell the difference is if you go to the</p> <p>20 term "Qdt cash," those are uninsured cash paying</p> <p>21 purchasers.</p> <p>22 THE WITNESS: And for the court</p> <p>23 reporter, you should actually highlight the</p> <p>24 first row. Dt cash equals uninsured cash</p> <p>25 paying purchasers.</p>

<p style="text-align: right;">Page 82</p> <p>1 BY MS. KAPKE:</p> <p>2 Q Okay. And this --</p> <p>3 A Hold on, just to make sure that we're</p> <p>4 on the same page.</p> <p>5 And then for people who are insured,</p> <p>6 sometimes they don't have to pay anything when they</p> <p>7 get their prescription filled, particularly for</p> <p>8 really low-cost generic drugs. And sometimes they</p> <p>9 are still required by their insurer to pay a</p> <p>10 co-insurance and a -- or a co-payment amount, and</p> <p>11 then their insurer may pay the remainder.</p> <p>12 That is the distinction that we are</p> <p>13 making here -- or that I am making here.</p> <p>14 Q Thank you. That's helpful.</p> <p>15 Is there a difference between a co-pay</p> <p>16 and a co-insurance?</p> <p>17 A Yes.</p> <p>18 Q What is that?</p> <p>19 A So co-payments tend to be flat. In</p> <p>20 other words, \$5 for every -- every generic</p> <p>21 prescription or \$1 for every generic prescription.</p> <p>22 Whereas co-insurance is a percentage of the total</p> <p>23 paid amount or the total charge for their</p> <p>24 prescription. So it's -- to make it really</p> <p>25 concrete, it will be 15 percent of the total paid</p>	<p style="text-align: right;">Page 84</p> <p>1 So the economic price for damages</p> <p>2 equals the price of each at-issue prescription sold</p> <p>3 and paid. That relates to the liability damages</p> <p>4 that you offered up a formula for, not the unjust</p> <p>5 enrichment damages that you offered an opinion on;</p> <p>6 is that correct?</p> <p>7 MR. HONIK: Object to form.</p> <p>8 A I don't follow your question.</p> <p>9 BY MS. KAPKE:</p> <p>10 Q Okay. I'll -- I'll withdraw it.</p> <p>11 Okay. Let's go to the unjust</p> <p>12 enrichment formula. I don't remember what paragraph</p> <p>13 that is.</p> <p>14 MR. HONIK: 63.</p> <p>15 MS. KAPKE: Thanks. Thank you, Ruben.</p> <p>16 BY MS. KAPKE:</p> <p>17 Q The basic formula you list here is</p> <p>18 revenue minus costs, and then you expand that out to</p> <p>19 provide additional detail. And I want to ask about,</p> <p>20 first, revenue.</p> <p>21 To determine revenue, you offer a</p> <p>22 formula of average out-of-pocket costs for Unit 2</p> <p>23 consumers of product d sold by the retailer over</p> <p>24 time period t. In this formula, does this average</p> <p>25 out --</p>
<p style="text-align: right;">Page 83</p> <p>1 amount.</p> <p>2 Q Got it. Thank you.</p> <p>3 Okay. Let's go to Paragraph 56 of</p> <p>4 your report. And can you read to yourself</p> <p>5 the -- that paragraph?</p> <p>6 A So that's finished.</p> <p>7 Q Let me know when you're done.</p> <p>8 MR. HONIK: It's a request. She'd</p> <p>9 like you to read it.</p> <p>10 THE WITNESS: Oh, okay. It's a</p> <p>11 request, all right. Just -- just following.</p> <p>12 MR. HONIK: Yeah.</p> <p>13 THE WITNESS: Okay.</p> <p>14 BY MS. KAPKE:</p> <p>15 Q Are you alleging that the retail</p> <p>16 pharmacy defendants committed fraud?</p> <p>17 MR. HONIK: Object to the form and to</p> <p>18 the extent it calls for a legal conclusion.</p> <p>19 You can answer.</p> <p>20 THE WITNESS: We already talked about</p> <p>21 this multiple times. I was asked to assume</p> <p>22 what was in the complaint and discussed in my</p> <p>23 Paragraphs 1, 2 and 3.</p> <p>24 BY MS. KAPKE:</p> <p>25 Q Got it.</p>	<p style="text-align: right;">Page 85</p> <p>1 A I don't see that. I'm sorry.</p> <p>2 So actually, I -- I define retail</p> <p>3 revenue of product -- product d, sold to consumers</p> <p>4 over time period t. Is that what you're referring</p> <p>5 to?</p> <p>6 Q Uh-huh.</p> <p>7 A Okay. And then I go on to talk about</p> <p>8 revenue expressed in Formula 5.</p> <p>9 Q Correct.</p> <p>10 A Correct. Okay.</p> <p>11 Q And in Formula 5, the consumer, PPU,</p> <p>12 is the average out-of-pocket cost per unit to</p> <p>13 consumers of product d sold by the retailer over</p> <p>14 time period t?</p> <p>15 MR. HONIK: Object to form.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: That's what it says</p> <p>18 here.</p> <p>19 BY MS. KAPKE:</p> <p>20 Q Okay. Does that average out-of-pocket</p> <p>21 cost per unit to consumers in your formula include</p> <p>22 only class members or all individuals who are</p> <p>23 dispensed at-issue valsartan?</p> <p>24 MR. HONIK: Object to form and to the</p> <p>25 extent it calls for a legal conclusion.</p>

<p style="text-align: right;">Page 86</p> <p>1 You can answer.</p> <p>2 THE WITNESS: I'm sorry, I don't</p> <p>3 understand the question you're asking. Can you</p> <p>4 please clarify?</p> <p>5 BY MS. KAPKE:</p> <p>6 Q For purposes of your formula, when</p> <p>7 you're calculating the average out-of-pocket cost</p> <p>8 per unit to consumers, are you including in</p> <p>9 consumers, in your theoretical world, all consumers</p> <p>10 of at-issue valsartan or only class members?</p> <p>11 MR. HONIK: Object to form, calls for</p> <p>12 a legal conclusion.</p> <p>13 You may answer.</p> <p>14 THE WITNESS: I mean, as a -- as a</p> <p>15 mechanical concern, we're only -- or I'm only</p> <p>16 calculating based on consumers that paid for</p> <p>17 the at-issue drugs in the at-issue time period,</p> <p>18 their out-of-pocket cost.</p> <p>19 BY MS. KAPKE:</p> <p>20 Q Would the average out-of-pocket cost</p> <p>21 include consumers who paid nothing?</p> <p>22 MR. HONIK: Object to the form, and</p> <p>23 class membership is a legal matter, beyond the</p> <p>24 scope.</p> <p>25 THE WITNESS: I don't understand what</p>	<p style="text-align: right;">Page 88</p> <p>1 theoretical perspective, saying that you need to</p> <p>2 factor in the average cost of product -- the average</p> <p>3 out-of-pocket cost per unit to consumers, when</p> <p>4 you're doing that average, are you including</p> <p>5 consumers --</p> <p>6 A In theory -- in theory or in practice?</p> <p>7 Q In theory.</p> <p>8 A Okay.</p> <p>9 Q In theory, does your average include</p> <p>10 those consumers who paid nothing?</p> <p>11 MR. HONIK: Object to the form.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: So by definition,</p> <p>14 mechanically, they would contribute 0, right?</p> <p>15 And so there is no payment made.</p> <p>16 BY MS. KAPKE:</p> <p>17 Q So do you include them in the</p> <p>18 denominator?</p> <p>19 A They fall out of the denominator in</p> <p>20 theory because they pay 0.</p> <p>21 Q Okay. I want to go to the formula to</p> <p>22 determine costs in your report.</p> <p>23 So retailer costs of dispensing</p> <p>24 product d to consumers over time period t, do you</p> <p>25 see that?</p>
<p style="text-align: right;">Page 87</p> <p>1 you're asking. I'm sorry.</p> <p>2 MS. KAPKE: Okay. And, Ruben, I'm</p> <p>3 going to just ask a question that's untethered</p> <p>4 to my prior questions.</p> <p>5 BY MS. KAPKE:</p> <p>6 Q So in looking at this formula --</p> <p>7 MR. HONIK: Does "untethered" mean</p> <p>8 crazy?</p> <p>9 MS. KAPKE: No.</p> <p>10 BY MS. KAPKE:</p> <p>11 Q I just want to -- I want to try and</p> <p>12 figure out this -- how you're deriving average</p> <p>13 out-of-pocket cost per unit to consumers.</p> <p>14 MR. HONIK: Okay.</p> <p>15 THE WITNESS: There's a formula. Then</p> <p>16 there's a mechanical calculation. Those are</p> <p>17 two different things, right?</p> <p>18 MR. HONIK: That's the mash-up</p> <p>19 problem, Kara. You're mashing up two things.</p> <p>20 THE WITNESS: Yeah. I don't --</p> <p>21 MS. KAPKE: Okay.</p> <p>22 MR. HONIK: I'm sure Dr. Conti can</p> <p>23 explain it to you though.</p> <p>24 BY MS. KAPKE:</p> <p>25 Q Okay. When you are, from a</p>	<p style="text-align: right;">Page 89</p> <p>1 A Yes.</p> <p>2 Q Are you referring in your formula</p> <p>3 here, from the theoretical perspective, only to the</p> <p>4 amount of money that a pharmacy would pay to a</p> <p>5 wholesaler or directly to a manufacturer for the</p> <p>6 dispensed product?</p> <p>7 A Go down to Formula 6 on the next page,</p> <p>8 and you can see how I defined costs. Retail costs</p> <p>9 of dispensing to consumers can be expressed in</p> <p>10 Formula 6 as a function of the quantity of units of</p> <p>11 product d sold to consumer over time period t and</p> <p>12 the average retailer cost per unit of product d over</p> <p>13 time period t to dispense to consumers. It is the</p> <p>14 cost of dispensing.</p> <p>15 Q And that would include what?</p> <p>16 A Well, the retailers took</p> <p>17 out -- interpreted that as the dispensing fee and</p> <p>18 took the dispensing fee for each prescription out of</p> <p>19 the data that was provided to us.</p> <p>20 Q I want to -- I want to remove the</p> <p>21 mechanical aspects and just talk about this from a</p> <p>22 theoretical perspective.</p> <p>23 If you are -- are looking at this from</p> <p>24 a purely academic perspective, what do you want to</p> <p>25 see in terms of defining retailer costs for purposes</p>

<p style="text-align: right;">Page 90</p> <p>1 of this formula?</p> <p>2 MR. HONIK: Object to form.</p> <p>3 THE WITNESS: I'm not calculating</p> <p>4 retailer costs here. I'm talking -- I'm</p> <p>5 referring to dispensing costs. They are</p> <p>6 different things.</p> <p>7 BY MS. KAPKE:</p> <p>8 Q Okay.</p> <p>9 A I mean, that's what's listed here.</p> <p>10 Retailer cost of this dispensing to consumers,</p> <p>11 that's -- that's what I'm -- that's the object in</p> <p>12 theory that I'm referring to.</p> <p>13 Q Okay. And the same question; taking</p> <p>14 away the mechanical aspect of this, in theory, from</p> <p>15 a purely academic perspective, what do you want to</p> <p>16 see in terms of retailer cost of dispensing to</p> <p>17 consumers?</p> <p>18 MR. HONIK: Object to form.</p> <p>19 THE WITNESS: It's the unit cost of</p> <p>20 dispensing a given prescription to a given</p> <p>21 patient.</p> <p>22 BY MS. KAPKE:</p> <p>23 Q What goes into that?</p> <p>24 A The marginal cost of dispensing will</p> <p>25 be the labor cost of filling the -- the vial and</p>	<p style="text-align: right;">Page 92</p> <p>1 those are point of sale costs, because my</p> <p>2 understanding is that -- is that they are not.</p> <p>3 BY MS. KAPKE:</p> <p>4 Q I'm asking you if -- what your formula</p> <p>5 takes into consideration.</p> <p>6 A I already defined that. It's the cost</p> <p>7 of dispensing a product to the consumer.</p> <p>8 Q Okay. So if -- and let's just take a</p> <p>9 hypothetical --</p> <p>10 A Another hypothetical.</p> <p>11 Q -- outside -- outside of valsartan.</p> <p>12 Say a drug -- say a pharmacy purchases</p> <p>13 a drug from -- directly from a manufacturer for \$10</p> <p>14 and then sells that drug to an uninsured customer</p> <p>15 for \$20. And say that the dispensing costs are \$5,</p> <p>16 and we're in this weird world where we know that the</p> <p>17 dispensing costs are \$5. Is the profit, under your</p> <p>18 formula, \$5 or \$10?</p> <p>19 MR. HONIK: Object to form.</p> <p>20 THE WITNESS: Okay. So you have a</p> <p>21 very -- that is -- that is a hypothetical that</p> <p>22 is bizarre in many ways. And I'm not aware of</p> <p>23 a generic drug having a dispensing fee of \$5</p> <p>24 ever associated with it. So let's just</p> <p>25 dispense it.</p>
<p style="text-align: right;">Page 91</p> <p>1 actually giving it to the patient. It might include</p> <p>2 some additional costs as well. But they are</p> <p>3 marginal -- marginal to the dispensing of an actual</p> <p>4 unit to a patient at the point of sale.</p> <p>5 THE COURT REPORTER: I'm sorry?</p> <p>6 THE WITNESS: At -- excuse me -- the</p> <p>7 point of sale.</p> <p>8 THE COURT REPORTER: Thank you.</p> <p>9 THE WITNESS: It can be the cost of</p> <p>10 the vial itself. It can be the cost of a paper</p> <p>11 bag. It can be the cost of the clerk sitting</p> <p>12 at the pharmacy counter actually giving it to</p> <p>13 the patient and ringing them up for the charge.</p> <p>14 It could be the incremental cost of the</p> <p>15 pharmacist, actually their time inputting the</p> <p>16 drug into the -- the unit, and then into the</p> <p>17 bag that they get at the pharmacy counter.</p> <p>18 Those are dispensing costs.</p> <p>19 BY MS. KAPKE:</p> <p>20 Q Does your formula take into account,</p> <p>21 in addition to dispensing costs, the actual cost of</p> <p>22 the drug that retailer pharmacy defendants would pay</p> <p>23 to whomever they obtained the drug for -- from?</p> <p>24 MR. HONIK: Object to form.</p> <p>25 THE WITNESS: Are you saying that</p>	<p style="text-align: right;">Page 93</p> <p>1 At the end of the day, it is the</p> <p>2 cost -- the dispensing costs are the costs that</p> <p>3 are incremental to a given patient in a given</p> <p>4 drug at the point of sale.</p> <p>5 So as I mentioned before, it's the</p> <p>6 cost of putting the drug in the vial. It's the</p> <p>7 cost of putting it in the bag. It's the cost</p> <p>8 of printing the label and giving all the</p> <p>9 consumer information to the consumer. It might</p> <p>10 be the labor cost of the pharmacist talking to</p> <p>11 the patient about the benefits and side-effects</p> <p>12 of taking this drug relative to others, and</p> <p>13 side-effect profile of that drug at the point</p> <p>14 of sale. That's what I think dispensing cost</p> <p>15 means.</p> <p>16 BY MS. KAPKE:</p> <p>17 Q Thank you for that.</p> <p>18 And I'm -- I'm just trying to</p> <p>19 understand if your -- if the cost of procurement is</p> <p>20 included in your formula for cost?</p> <p>21 A Where do you see in my report that the</p> <p>22 cost of procurement is included in my definition of</p> <p>23 dispensing costs?</p> <p>24 Q I'm asking you a question.</p> <p>25 A I have defined dispensing cost five</p>

<p style="text-align: right;">Page 94</p> <p>1 separate times. It's also defined very clearly in 2 my report. This is a -- 3 Q I'm not asking you -- 4 A Excuse me. This is a term of art in 5 this field. I am using it correctly and precisely, 6 and I have restated over and over again the 7 definition of dispensing cost. 8 Q I understand that. 9 I'm not asking you if your -- so your 10 formula is revenue minus costs? 11 A No. My formula is retail cost of 12 dispensing to consumers. That is in Formula 6 -- 13 Q Okay. I'm looking at -- 14 A -- where I define the cost of 15 dispensing to the consumer at the point of sale. 16 It's the quantity of the unit times average retailer 17 cost per unit of dispensing to the consumer. 18 Dispensing to the consumer is a cost. Anyone who 19 knows anything about this industry knows what a 20 dispensing cost is. It's related to the labor and 21 capital that goes into handing a prescription of the 22 drug to a patient at the pharmacy counter. That is 23 what I am using here as cost. 24 Q Let's look at Formula 4, please. 25 A No. I'm not -- I mean, I'm happy to</p>	<p style="text-align: right;">Page 96</p> <p>1 out of the data they gave me. There's no -- this is 2 not a theoretical. This is an -- this relates to an 3 actual thing, that you, the retailers, know what it 4 is because you took it out of the data that was 5 provided to myself and my staff. 6 Q What are DIR fees? 7 A They are payments that can be made 8 between entities in the pharmaceutical industry. 9 Q Is it your understanding that DIR fees 10 are typically collected retrospectively after the 11 point of sale? 12 A My understanding is that there's a 13 range of different arrangements. 14 THE THE COURT REPORTER: There is or 15 there isn't a range? 16 THE WITNESS: There is a range of 17 different arrangements. And they only relate 18 to certain types of products and a certain type 19 of transaction and certain time periods. The 20 use of DIR fees have been growing over time. 21 BY MS. KAPKE: 22 Q Are there other fees besides DIR fees 23 that are assessed after the point of sale? 24 A For who to who? 25 Q For commercial plans.</p>
<p style="text-align: right;">Page 95</p> <p>1 go back to Formula 4. But, again, I define the cost 2 in Formula 4 as related to Formula 6, the cost of 3 dispensing to consumers. They are one and the same. 4 Q Okay. That's what I'm trying to 5 understand. And -- and I'm sorry if I am -- I -- I 6 don't under- -- I don't understand the answer to 7 this question. 8 Does the formula in Formula 4, when it 9 says revenue minus costs, does costs there refer to 10 any costs other than the dispensing costs that you 11 have identified for me and explained? 12 A Again, the cost defined in Formula 4, 13 cost dt, is defined underneath cost dt equals the 14 retailer cost of dispensing product d to consumers 15 over time period t. 16 I then go on to define cost in more 17 detail where I say, retailer costs of dispensing to 18 consumers can be expressed in Formula 6 as cost dt 19 equals Qdt, the quantity of units of product d sold 20 to consumers over time period t times the retailer 21 CPUdt, the average retailer cost per unit of product 22 d over time period t to dispense to consumers. I 23 can't -- I can't be any clearer than that. 24 And clearly, the retailers know what a 25 dispensing fee is because they actually took that</p>	<p style="text-align: right;">Page 97</p> <p>1 A I don't -- I don't understand -- I 2 don't understand the question. 3 Q Okay. I'll withdraw it. 4 Can you explain, generally, what a 5 dispensing fee is? 6 MR. HONIK: Objection, asked and 7 answered. 8 THE WITNESS: Like, seven times, but 9 who's counting? 10 So a dispensing fee is a fee that is 11 charged to consumers and to third-party payors 12 for the dispensing of a prescription at the 13 point of sale. 14 BY MS. KAPKE: 15 Q Who do you believe pays the dispensing 16 fee? 17 A Well, I'll tell you that I went to the 18 pharmacy earlier this week, and I paid the 19 dispensing fee. So usually for oral drugs, 20 consumers at the point of sale pay dispensing fees 21 if they -- 22 THE THE COURT REPORTER: If they what? 23 THE WITNESS: If they are required to. 24 If they have insurance that covers those 25 dispensing fees, insurers will pay for those</p>

Page 98	Page 100
<p>1 dispensing fees. It depends on the 2 arrangement. 3 BY MS. KAPKE: 4 Q What pharmacy do you -- did you use? 5 A CVS. They're my favorite. 6 Q Who determines what the dispensing fee 7 is? 8 A I don't know. I'm assuming the 9 pharmacy itself, but I don't know. 10 Q Is it negotiated over time? 11 MR. HONIK: Object to form. 12 THE WITNESS: I don't know. 13 BY MS. KAPKE: 14 Q How much do you think a dispensing fee 15 typically amounts to? 16 A For an oral generic drug, it can be on 17 the order of cents or a dollar. Usually, it's 18 nominal, but it really depends. 19 Q In terms of your profit calculations, 20 did the cost of the ingredients factor in in any 21 way? 22 MR. HONIK: Object to the form, asked 23 and answered. 24 THE WITNESS: Again, I have defined 25 the cost related to the dispensing fee.</p>	<p>1 THE WITNESS: That's great. Thank 2 you. 3 THE VIDEOGRAPHER: The time is 11:41. 4 This ends Media Number 2. We're going off the 5 record. 6 (Whereupon, a short break was taken.) 7 MR. HONIK: Plaintiffs are back at 8 11:46 and are ready to proceed. 9 THE VIDEOGRAPHER: The time is 11:49. 10 This begins Media Unit Number 3. We're back on 11 the record. 12 EXAMINATION BY MR. CAMPBELL: 13 Q Okay. Good morning, still, Dr. Conti. 14 My name is Dan Campbell. I'm going to ask you some 15 questions about your opinions -- 16 THE COURT REPORTER: I'm sorry. You 17 trailed off. You're going to ask questions... 18 BY MR. CAMPBELL: 19 Q Regarding your opinions about the 20 wholesalers in this case. 21 A Okay. 22 Q Can you hear me okay, Dr. Conti? 23 A Yes. 24 Q Okay. 25 MR. CAMPBELL: And, Madam Court</p>
Page 99	Page 101
<p>1 Dispensing fees, as I understand them, do not 2 relate to the cost of the ingredient, but might 3 relate to whether the product is generic or 4 branded or the formulation of the product. 5 Because, again, there's labor costs associated 6 with that dispensing fee, and some drugs 7 require more labor costs and more capital 8 to -- to deal with them. 9 BY MS. KAPKE: 10 Q You mentioned a couple of times how 11 products are commonly repackaged and relabeled by 12 private label distributors and retailers. Are you 13 making any allegations in this case that CVS, or any 14 retail pharmacy defendant in this case, repackaged 15 or relabeled valsartan? 16 MR. HONIK: Object to the form. 17 THE WITNESS: I don't know. 18 MS. KAPKE: I am, for purposes of 19 time, am going to pass the witness. 20 MR. HONIK: Thank you. 21 THE WITNESS: Thank you. 22 I think now is a good time for me to 23 take a break then, please. 24 MR. HONIK: Okay. Five minutes 25 enough?</p>	<p>1 Reporter, can you hear me okay, also? 2 THE COURT REPORTER: You're a little 3 low, but I can hear you. 4 MR. CAMPBELL: Okay. I pulled the 5 microphone as close as I can get it here, so I 6 will do the best I can. 7 BY MR. CAMPBELL: 8 Q So, Dr. Conti, you talked a lot 9 yesterday about your role as a professor, your 10 coursework, your class work. How much of that 11 coursework, that class work, involves 12 wholesaler-specific issues? 13 A I have spent some time understanding a 14 wholesaler's role in this industry. I have had the 15 pleasure of working with some folks at Cardinal and 16 at AmerisourceBergen and in multiple contexts. 17 THE THE COURT REPORTER: Did you say 18 -- did you say Amerisource? 19 THE WITNESS: AmerisourceBergen. 20 THE COURT REPORTER: Okay. 21 BY MR. CAMPBELL: 22 Q In what sort of context -- 23 A And Cardinal. 24 Q Thank you. 25 A Yeah.</p>

<p style="text-align: right;">Page 102</p> <p>1 Q In what context did you work with</p> <p>2 those folks at Cardinal and AmerisourceBergen?</p> <p>3 A Again, just in the normal course of my</p> <p>4 business, I spend a lot of time trying to understand</p> <p>5 how this industry works and the role wholesalers has</p> <p>6 is part of the -- part of the ecosystem.</p> <p>7 Q Were you --</p> <p>8 A So I can be -- I can be more specific.</p> <p>9 I've been on -- I've been on panels and conferences.</p> <p>10 I've been in closed-door meetings, discussing</p> <p>11 various issues related to reimbursement, financing,</p> <p>12 organization, regulation, where wholesaler</p> <p>13 representatives have been there. And I know</p> <p>14 something about the wholesaler data that -- that</p> <p>15 wholesalers such as Cardinal and AmerisourceBergen</p> <p>16 maintain. What else should I tell you?</p> <p>17 I teach about the role of wholesalers</p> <p>18 in this ecosystem and have had the pleasure of</p> <p>19 reviewing shareholder reports of AmerisourceBergen,</p> <p>20 Cardinal and other public wholesalers operating in</p> <p>21 the U.S. market.</p> <p>22 Q And so you mentioned that earlier this</p> <p>23 morning. Those are the public finance reports that</p> <p>24 you reviewed either last night or this morning?</p> <p>25 A No, I mean -- so, again, I'm talking</p>	<p style="text-align: right;">Page 104</p> <p>1 Q Okay. All right. We may follow up</p> <p>2 with your counsel on that.</p> <p>3 A Sure.</p> <p>4 Q Have you -- you mentioned earlier</p> <p>5 today a study that you did, I think when you were a</p> <p>6 professor at Chicago, involving Walgreens and data</p> <p>7 that you were working with from -- from Walgreens.</p> <p>8 Do you remember that discussion?</p> <p>9 A Yes.</p> <p>10 Q Okay. Have you ever done any sort of</p> <p>11 similar study with the wholesaler or with wholesaler</p> <p>12 data like the Walgreens study?</p> <p>13 A I have -- so, I have never published</p> <p>14 work in --</p> <p>15 THE THE COURT REPORTER: I'm sorry. I</p> <p>16 have never published working...</p> <p>17 THE WITNESS: Work in collaboration</p> <p>18 with the wholesalers who are members in this</p> <p>19 matter. I have looked at wholesaler data where</p> <p>20 the -- it was shared with me at a screen share.</p> <p>21 BY MR. CAMPBELL:</p> <p>22 Q What sort of wholesale data was shared</p> <p>23 with you on a screen share?</p> <p>24 A Transaction data for specific drugs.</p> <p>25 Q Related to the drugs at-issue in this</p>
<p style="text-align: right;">Page 103</p> <p>1 generally. So part of my course that I teach on</p> <p>2 Strategy in the Pharmaceutical Industry requires</p> <p>3 that my students do shareholder report analysis.</p> <p>4 And we focus both on pharmaceutical manufacturers,</p> <p>5 but also other entities that are important in the</p> <p>6 supply chain, which include the wholesalers and also</p> <p>7 include some of the retailers that we've talked</p> <p>8 about.</p> <p>9 There are a handful of shareholder</p> <p>10 reports that I looked at over the past couple of</p> <p>11 days that include Mylan, Teva -- I think maybe one</p> <p>12 more of the defendant manufacturers. And I</p> <p>13 certainly looked over gross revenues of the retailer</p> <p>14 pharmacies as well.</p> <p>15 Q Do you remember any specific</p> <p>16 individuals at Cardinal or AmerisourceBergen at any</p> <p>17 of those conferences or panels when you were there</p> <p>18 with them?</p> <p>19 A Not off the top of my head. I am in</p> <p>20 email correspondence with a number of former</p> <p>21 executives working on some work related to private</p> <p>22 labeling activities for some drugs that went into</p> <p>23 short supply, but not ones that are related in this</p> <p>24 matter. I'm more than happy to tell you who those</p> <p>25 are. I just don't have them off the top of my head.</p>	<p style="text-align: right;">Page 105</p> <p>1 case?</p> <p>2 A No.</p> <p>3 Q And do you remember the components of</p> <p>4 the transaction data that were shared with you?</p> <p>5 A Yeah. There were drug names, units</p> <p>6 and --</p> <p>7 THE COURT REPORTER: And...</p> <p>8 THE WITNESS: Paid amounts.</p> <p>9 And there were also, I think,</p> <p>10 manufacturer names as well. But in this</p> <p>11 specific context, we were -- we were actually</p> <p>12 looking at the differences in --</p> <p>13 THE THE COURT REPORTER: I'm sorry.</p> <p>14 Somebody is shuffling papers.</p> <p>15 We were looking at the differences</p> <p>16 in...</p> <p>17 THE WITNESS: We were looking at</p> <p>18 transactions -- I'm sorry. There's a lot of</p> <p>19 background noise. I hear it too.</p> <p>20 There's -- there were transactions</p> <p>21 related to manufacturers and -- for specific</p> <p>22 drugs. And then the relabeling of certain</p> <p>23 product by the wholesaler distributors for</p> <p>24 certain types of product.</p> <p>25</p>

<p style="text-align: right;">Page 106</p> <p>1 BY MR. CAMPBELL:</p> <p>2 Q Were there any confidentiality</p> <p>3 agreements related to that data that you were shown?</p> <p>4 A I -- in at least one interaction, I</p> <p>5 did sign a confidentiality agreement. But it wasn't</p> <p>6 for any of the wholesalers that are named in this.</p> <p>7 Q You said that was a screen share. So</p> <p>8 did you take any documents back with you? Do you</p> <p>9 have any documents on your computer or on your desk</p> <p>10 or anything like that?</p> <p>11 A No. I wish, but no. Yeah.</p> <p>12 Q And was it that experience and looking</p> <p>13 at that data that informed your opinions here about</p> <p>14 the damages calculation as to wholesalers?</p> <p>15 A Well, we talked about this yesterday,</p> <p>16 that -- I mean, I've spent every day for the past</p> <p>17 20 years thinking about how this -- how this system</p> <p>18 works, and specifically how prescription drugs go</p> <p>19 from base ingredients to -- to API to fill and</p> <p>20 finish, manufacturing, you know, through the supply</p> <p>21 chain, which includes distributors and then,</p> <p>22 ultimately, to reach our pharmacies or to hospitals</p> <p>23 or to medical groups and then, finally, to be</p> <p>24 infused, injected or dispensed to consumers.</p> <p>25 Certainly, the role of wholesalers is</p>	<p style="text-align: right;">Page 108</p> <p>1 Q It took you many hours, also, to write</p> <p>2 the report, correct?</p> <p>3 A Yes.</p> <p>4 Q Okay. All right. Do you remember how</p> <p>5 much of that time you actually spent writing the</p> <p>6 last two pages of the report, which has the formulas</p> <p>7 for the wholesalers, the proposed formulas?</p> <p>8 A Yeah. I thought a lot about those</p> <p>9 last two -- those last two pages.</p> <p>10 Q Do you know the number of hours you</p> <p>11 spent on those last two pages?</p> <p>12 A No, sorry, not off the top of my head.</p> <p>13 As I told you, I -- I have been a little bit remiss</p> <p>14 in getting my time together. I like to double and</p> <p>15 triple check it before I submit it, and it's been a</p> <p>16 busy couple of months. So I don't know. I'm sorry.</p> <p>17 Q That's all right.</p> <p>18 And in the records that you do have of</p> <p>19 the time that you spent on the report, would they</p> <p>20 indicate which parts of the report you were working</p> <p>21 on?</p> <p>22 A Not really.</p> <p>23 Q So will we ever see an invoice, for</p> <p>24 example, that breaks down which portions of the</p> <p>25 report you were working on in a given time entry?</p>
<p style="text-align: right;">Page 107</p> <p>1 a very important one in this field, and one that I'm</p> <p>2 involved -- I routinely understand and -- and am</p> <p>3 thinking about in -- in my academic roles. So</p> <p>4 therefore, by definition, it informs how I think</p> <p>5 about their role in this case. But...</p> <p>6 Q Got you.</p> <p>7 A I actually haven't spent that much</p> <p>8 time writing about distributors and wholesalers, in</p> <p>9 part because the data is all --</p> <p>10 THE COURT REPORTER: The what?</p> <p>11 THE WITNESS: The data is opaque.</p> <p>12 It's not normally what we -- I have access to</p> <p>13 in my -- in the course of my daily research --</p> <p>14 research.</p> <p>15 BY MR. CAMPBELL:</p> <p>16 Q You mentioned yesterday that the</p> <p>17 report, which is, I think, Exhibit 5, that that</p> <p>18 report took you, I think you said many months to</p> <p>19 write. Do you remember that?</p> <p>20 A Yes.</p> <p>21 Q Okay. And we looked at some of the</p> <p>22 hours yesterday, and let's just say dozens of hours</p> <p>23 to write your report, right?</p> <p>24 A I don't understand your question. I'm</p> <p>25 sorry.</p>	<p style="text-align: right;">Page 109</p> <p>1 A Do you mean, like, Section 1, 2 and 3?</p> <p>2 Q Yes, or -- or by page number?</p> <p>3 A I haven't apportioned to that. That's</p> <p>4 just not how I work, so no.</p> <p>5 Q Okay. If you --</p> <p>6 MR. CAMPBELL: If Mr. or Ms. Tech</p> <p>7 could pull up the report, I think it's</p> <p>8 Exhibit 5. And, Dr. Conti, I'm going to refer</p> <p>9 you to Attachment B to start with, please.</p> <p>10 BY MR. CAMPBELL:</p> <p>11 Q Dr. Conti, let me know when you're at</p> <p>12 Attachment B.</p> <p>13 A Just give me a second.</p> <p>14 Q Sure.</p> <p>15 A Okay.</p> <p>16 Q And I'm going to stay on the first</p> <p>17 page of Attachment B, so you don't have to worry</p> <p>18 about flipping pages here. Do you see the section</p> <p>19 that's the second section that's called "Case</p> <p>20 Documents"?</p> <p>21 A Yes.</p> <p>22 Q All right. So in this section of case</p> <p>23 documents, is this a list of all the documents that</p> <p>24 are -- in this matter, in this case, that you --</p> <p>25 that you reviewed?</p>

<p style="text-align: right;">Page 110</p> <p>1 A Yes.</p> <p>2 Q So there are no documents coming out</p> <p>3 of this case that you reviewed but did not list?</p> <p>4 A Right. Other than in the course of</p> <p>5 normal events in my daily life, I know something</p> <p>6 about all of these -- all of the defendants.</p> <p>7 Defenses.</p> <p>8 Q Right. Okay. And so you list here</p> <p>9 one declaration of Matthew Sample. Do you see that?</p> <p>10 It's the second one listed.</p> <p>11 A Yes.</p> <p>12 Q Do you know who Matthew Sample is an</p> <p>13 employee of?</p> <p>14 A I don't, not off the top of my head.</p> <p>15 Oh, I do, actually. It's in Footnote 76, defendant</p> <p>16 wholesaler AmerisourceBergen Corporation represented</p> <p>17 that producing such data would be --</p> <p>18 THE COURT REPORTER: I'm sorry,</p> <p>19 Doctor. Producing such data would be...</p> <p>20 THE WITNESS: Sorry. Footnote 76, if</p> <p>21 we can go back to my main report.</p> <p>22 BY MR. CAMPBELL:</p> <p>23 Q And, Dr. Conti, you don't need to read</p> <p>24 it. I just wanted to ask you a simple question.</p> <p>25 Did you review any other -- or any declarations from</p>	<p style="text-align: right;">Page 112</p> <p>1 Cardinal Health, McKesson or AmerisourceBergen in</p> <p>2 this case, correct?</p> <p>3 A Correct.</p> <p>4 Q Did you ask to see any electronic data</p> <p>5 from any of them?</p> <p>6 A Yes.</p> <p>7 Q All right. And so who did you ask?</p> <p>8 A Counsel.</p> <p>9 Q What were you told?</p> <p>10 MR. HONIK: Let me note my -- note my</p> <p>11 objection. It invades the attorney work</p> <p>12 product and other privileges.</p> <p>13 But without waiver of that objection,</p> <p>14 she may answer.</p> <p>15 THE WITNESS: That there were -- that</p> <p>16 there was no --</p> <p>17 THE THE COURT REPORTER: That there</p> <p>18 was no...</p> <p>19 THE WITNESS: Data produced.</p> <p>20 BY MR. CAMPBELL:</p> <p>21 Q Let me refer you back in your report</p> <p>22 to Paragraph 3, early on in your report --</p> <p>23 MR. CAMPBELL: If the tech can get</p> <p>24 back to that area, please.</p> <p>25</p>
<p style="text-align: right;">Page 111</p> <p>1 any other wholesaler representatives --</p> <p>2 A Not -- not off the top --</p> <p>3 Q -- in this case?</p> <p>4 A Not off the top of my head.</p> <p>5 Q And did you review any documents that</p> <p>6 were produced by either Cardinal Health or McKesson</p> <p>7 or AmerisourceBergen?</p> <p>8 A No.</p> <p>9 Q Did you review any deposition</p> <p>10 testimony from any representatives of</p> <p>11 Cardinal Health, McKesson or AmerisourceBergen?</p> <p>12 A No.</p> <p>13 Q And a little bit further down, I</p> <p>14 believe on this first page of Attachment B -- I'm</p> <p>15 sorry. I misspoke earlier when I said we were going</p> <p>16 to stick on Page 1 of the Attachment B.</p> <p>17 If you can please go to Page 4 of</p> <p>18 Attachment B. Do you see Page 4 here, Dr. Conti?</p> <p>19 It has a section called "Electronic Data"?</p> <p>20 A I see that.</p> <p>21 Q And it goes over Page 5 for several</p> <p>22 pages after that, correct?</p> <p>23 A Correct.</p> <p>24 Q I just want to confirm you did not</p> <p>25 review any electronic data from either</p>	<p style="text-align: right;">Page 113</p> <p>1 BY MR. CAMPBELL:</p> <p>2 Q And I just want to ask you, Dr. Conti,</p> <p>3 while -- I'll set it up for you while the tech is</p> <p>4 going back. I want to ask you about some of the</p> <p>5 assumptions regarding wholesalers specifically.</p> <p>6 Okay?</p> <p>7 A Okay.</p> <p>8 Q So you say in Paragraph 3 that,</p> <p>9 "Plaintiffs' counsel have also asked me to assume</p> <p>10 that a subset of these at-issue valsartan products</p> <p>11 were sold by defendants AmerisourceBergen Co,</p> <p>12 Cardinal Health and McKesson Co, collectively</p> <p>13 referred to as the defendant wholesalers."</p> <p>14 Do you see that Paragraph 3?</p> <p>15 A I do.</p> <p>16 Q What do you mean in here when you</p> <p>17 wrote the word "subset"?</p> <p>18 A That some of the at-issue products</p> <p>19 were sold to -- in the...</p> <p>20 THE THE COURT REPORTER: I'm sorry.</p> <p>21 In the...</p> <p>22 THE WITNESS: I said the at-issue</p> <p>23 drugs were sold by the manufacturers to these</p> <p>24 specific wholesalers. There were other --</p> <p>25 there are other wholesalers, obviously,</p>

<p style="text-align: right;">Page 114</p> <p>1 involved in the U.S. market. And at a given</p> <p>2 period in time, manufacturers are going to sell</p> <p>3 specific drugs to specific wholesalers.</p> <p>4 That's what I mean.</p> <p>5 BY MR. CAMPBELL:</p> <p>6 Q And then there were also transactions</p> <p>7 where the manufacturer sold directly to the retail</p> <p>8 pharmacies?</p> <p>9 A Correct.</p> <p>10 Q Were you asked to assume any</p> <p>11 particular percentage of this subset that were sold</p> <p>12 through the wholesalers?</p> <p>13 A I was -- I was not, and that's because</p> <p>14 during the at-issue time period, 2012 through 2018,</p> <p>15 there was very significant asymmetric information.</p> <p>16 And so the contamination of the products was</p> <p>17 not -- was known by the manufacturers, but they were</p> <p>18 not known by other members of the supply chain.</p> <p>19 THE THE COURT REPORTER: Of the...</p> <p>20 THE WITNESS: Supply chain.</p> <p>21 BY MR. CAMPBELL:</p> <p>22 Q Were you told to -- in this case, in</p> <p>23 rendering your opinions in this declaration, were</p> <p>24 you told to assume anything about the wholesalers'</p> <p>25 conduct?</p>	<p style="text-align: right;">Page 116</p> <p>1 MR. HONIK: Object to the form.</p> <p>2 THE WITNESS: Correct. I don't -- I</p> <p>3 don't actually mechanically do any</p> <p>4 calculations. All I'm doing is laying out how</p> <p>5 I would think about calculating unjust</p> <p>6 enrichment in this matter for these specific</p> <p>7 drugs at-issue in this specific period.</p> <p>8 BY MR. CAMPBELL:</p> <p>9 Q In any of the prior cases where you</p> <p>10 have been an expert, have you similarly attempted to</p> <p>11 calculate unjust enrichment damages for wholesalers?</p> <p>12 A Not that I can recall off the top of</p> <p>13 my head.</p> <p>14 MR. CAMPBELL: If I could please ask</p> <p>15 the tech to go to Paragraph 50 of your report.</p> <p>16 BY MR. CAMPBELL:</p> <p>17 Q And, Dr. Conti, please just let me</p> <p>18 know when you're there.</p> <p>19 A Okay.</p> <p>20 Q And I actually want to refer you to</p> <p>21 the second sentence in Paragraph 50, "Given that the</p> <p>22 at-issue valsartan products are small molecule</p> <p>23 orally formulated generic drugs, the majority of</p> <p>24 purchases are made by pharmacies from</p> <p>25 wholesalers/distributors."</p>
<p style="text-align: right;">Page 115</p> <p>1 A Other than what was laid out in the</p> <p>2 complaint and listed in my Paragraphs 1, 2 and 3.</p> <p>3 Q So you are not offering any opinions</p> <p>4 yourself in this declaration about the wholesalers'</p> <p>5 conduct in this case, correct?</p> <p>6 MR. HONIK: Object to the form.</p> <p>7 You can answer.</p> <p>8 THE WITNESS: Correct. Correct. This</p> <p>9 is...</p> <p>10 THE THE COURT REPORTER: Can you</p> <p>11 repeat that, please?</p> <p>12 THE WITNESS: Sure.</p> <p>13 It's on instruction or for -- it's on</p> <p>14 instruction by counsel.</p> <p>15 BY MR. CAMPBELL:</p> <p>16 Q You're not offering any opinions</p> <p>17 whether wholesalers are liable for unjust</p> <p>18 enrichment?</p> <p>19 A I'm not a lawyer, sir, so no. I was</p> <p>20 asked to assume certain details for the purposes of</p> <p>21 my report.</p> <p>22 Q So your opinions, with respect to the</p> <p>23 wholesalers in this case, is limited to essentially</p> <p>24 proposing a formula for calculating unjust</p> <p>25 enrichment damages?</p>	<p style="text-align: right;">Page 117</p> <p>1 Do you see that sentence?</p> <p>2 A Yes.</p> <p>3 Q Why does the fact, as you write here,</p> <p>4 that the at-issue valsartan products are small</p> <p>5 molecule orally formulated generic drugs -- why does</p> <p>6 that mean that the majority of purchases were made</p> <p>7 by pharmacies from wholesalers and distributors?</p> <p>8 A Yeah. So the -- for me, the context</p> <p>9 is important. So the supply chain for specialty</p> <p>10 drugs that are infused or injected can be different.</p> <p>11 And so those products can be handled by different</p> <p>12 distributors or group purchasing organizations.</p> <p>13 Usually, they have different storage requirements,</p> <p>14 and their end consumer is different too. It's</p> <p>15 usually hospitals or outpatient clinics, maybe some</p> <p>16 specialty pharmacies. It's just a -- it's just a</p> <p>17 different supply chain.</p> <p>18 The orally formulated generic drugs</p> <p>19 are the ones that are really are at-issue in this</p> <p>20 matter, and here, they are largely going through the</p> <p>21 distributors, as listed here.</p> <p>22 Q And you just said, "largely." And in</p> <p>23 your report, you say, "majority," but you don't know</p> <p>24 exactly what the percentage is, right?</p> <p>25 A I think in the Deloitte and Touche</p>

<p style="text-align: right;">Page 118</p> <p>1 article, I -- I footnote to this paragraph. It has,</p> <p>2 "A number of distributors handles 92 percent of</p> <p>3 pharmaceutical sales in the U.S. market." And that</p> <p>4 is largely related to orals. It's not related to</p> <p>5 these specialty drugs. If you actually look at the</p> <p>6 backup of the Deloitte paper, the Deloitte paper</p> <p>7 also talks about 11 million prescription units being</p> <p>8 sold each day and handled through the distributors</p> <p>9 at-issue -- such as these in this case.</p> <p>10 Q That article is talking about industry</p> <p>11 wide, right?</p> <p>12 A Industry wide, absolutely.</p> <p>13 Q Okay. So for the at-issue valsartan</p> <p>14 products in this case, you have no idea what the</p> <p>15 percentage is that were sold through the</p> <p>16 wholesalers?</p> <p>17 A Well, so again, in that same footnote,</p> <p>18 Footnote 47, the first paragraph, Mylan and Teva in</p> <p>19 their public reporting talk about total sales going</p> <p>20 through the -- through distributors. Shareholder</p> <p>21 reports specifically report those type of sales in</p> <p>22 aggregate and not for specific drug NDC codes, which</p> <p>23 is really at-issue here. So we know one thing, but</p> <p>24 we don't know at the actual NDC batch lot number</p> <p>25 that we -- we might switch to.</p>	<p style="text-align: right;">Page 120</p> <p>1 the supply chain. Is that correct? Is that what</p> <p>2 you're asking?</p> <p>3 Q Yes, if you could answer that</p> <p>4 question; is that correct?</p> <p>5 A Yes, that is correct.</p> <p>6 Q Okay. All right.</p> <p>7 A Again, as a general matter.</p> <p>8 Q As a general matter. Great.</p> <p>9 So with respect to its role in the</p> <p>10 supply chain, wholesalers are not putting the</p> <p>11 product out into the -- into the consumer market?</p> <p>12 MR. HONIK: Object to the form, may</p> <p>13 call for a legal conclusion.</p> <p>14 You can answer.</p> <p>15 THE WITNESS: Thank you.</p> <p>16 So -- well, I mean, I guess -- I mean,</p> <p>17 they are an important part of the supply chain,</p> <p>18 and wholesalers do take --</p> <p>19 THE COURT REPORTER: They do take</p> <p>20 what?</p> <p>21 THE WITNESS: Do take title from</p> <p>22 manufacturers. They hold those drugs in a</p> <p>23 warehouse, usually, and then hand them off to</p> <p>24 the resale -- to the -- sorry -- to the retail</p> <p>25 pharmacies. Or it might be a little bit of an</p>
<p style="text-align: right;">Page 119</p> <p>1 Q Okay. So for the at-issue valsartan</p> <p>2 products here, we don't know what the percentage is</p> <p>3 that were sold through the wholesaler distributors?</p> <p>4 A Right. We just have these industry</p> <p>5 averages and averages that are specific to the</p> <p>6 manufacturers, not at the NDC code level.</p> <p>7 Q And just to confirm, wholesalers, they</p> <p>8 don't sell these products into the consumer market,</p> <p>9 correct?</p> <p>10 MR. HONIK: Object to the form, it may</p> <p>11 call for a legal conclusion.</p> <p>12 THE WITNESS: I'm sorry. What do you</p> <p>13 mean by that?</p> <p>14 BY MR. CAMPBELL:</p> <p>15 Q I couldn't hear what you said. You</p> <p>16 didn't know what I meant. So what was your</p> <p>17 question?</p> <p>18 A Can you please ask it again? Thank</p> <p>19 you.</p> <p>20 Q Yes. Yes. Just to confirm,</p> <p>21 wholesalers do not sell these products directly to</p> <p>22 patients, correct?</p> <p>23 A Okay. So I think what you mean is</p> <p>24 that, as a general matter, retail pharmacies sell to</p> <p>25 consumers. Wholesalers occupy a different art of</p>	<p style="text-align: right;">Page 121</p> <p>1 accounting mix where they take title, but</p> <p>2 actually, the manufacturers drop ship directly</p> <p>3 from their warehouse to the --</p> <p>4 THE COURT REPORTER: To the what?</p> <p>5 THE WITNESS: To the retail</p> <p>6 pharmacies.</p> <p>7 BY MR. CAMPBELL:</p> <p>8 Q And then it's the retail pharmacies</p> <p>9 that sell to the patients, correct?</p> <p>10 A That's my understanding -- well,</p> <p>11 for -- for products that are sold in the retail</p> <p>12 class of trade. There are -- there are drugs that</p> <p>13 are sold to physicians and hospitals or specialty</p> <p>14 pharmacies -- pharmacies that have a slightly</p> <p>15 different distribution chain. But that's not what</p> <p>16 we're -- that's largely not what we're talking about</p> <p>17 here.</p> <p>18 Q These products at-issue in this case,</p> <p>19 the at-issue valsartan products, were sold by the</p> <p>20 retail pharmacies to the consumers, to patients?</p> <p>21 A Right. So there probably are</p> <p>22 valsartan that were sold -- there are probably</p> <p>23 at-issue valsartan products that were sold to</p> <p>24 hospitals or sold to outpatient clinics for their</p> <p>25 own stocking to take care of patients. But as a</p>

<p style="text-align: right;">Page 122</p> <p>1 mechanical matter, my damage estimation is focused</p> <p>2 on largely the retail class of trade.</p> <p>3 I can actually see a cross trade in</p> <p>4 the IQVIA data, but we're largely focused on the</p> <p>5 retail class of trade.</p> <p>6 Q All right.</p> <p>7 MR. CAMPBELL: If you can -- if the</p> <p>8 tech can, please, go to Paragraph 80.</p> <p>9 BY MR. CAMPBELL:</p> <p>10 Q And -- and if you could go there too,</p> <p>11 Dr. Conti, please.</p> <p>12 A Sure. I'm trying to follow. Hold on.</p> <p>13 Okay.</p> <p>14 Q All right. And I'm really just going</p> <p>15 to focus on this first sentence here at 80 where you</p> <p>16 wrote, "I have also been asked by plaintiffs'</p> <p>17 counsel to develop a methodology for calculating</p> <p>18 defendant wholesaler unjust enrichment damages for</p> <p>19 the at-issue valsartan products."</p> <p>20 Do you see that?</p> <p>21 A Yes.</p> <p>22 Q What is your understanding of unjust</p> <p>23 enrichment?</p> <p>24 MR. HONIK: Note my objection to the</p> <p>25 extent it calls for a legal opinion.</p>	<p style="text-align: right;">Page 124</p> <p>1 damages, are you aware that that might vary from</p> <p>2 state to state, depending on the state law?</p> <p>3 MR. HONIK: Note my objection to the</p> <p>4 extent it calls for a legal opinion.</p> <p>5 THE WITNESS: Nothing in the U.S. is</p> <p>6 easy. But basically, I would say, yes. I</p> <p>7 understand generally that state -- there are</p> <p>8 state rules related to damage calculations and</p> <p>9 specifically related to liability and also</p> <p>10 unjust enrichment. But, again, I'm not a</p> <p>11 lawyer. I understand these as a mechanical</p> <p>12 issue.</p> <p>13 BY MR. CAMPBELL:</p> <p>14 Q And did your proposed formula for</p> <p>15 calculating unjust enrichment damages as to</p> <p>16 wholesalers take into account, in any way, those</p> <p>17 differences from one state to another?</p> <p>18 MR. HONIK: Same objection as</p> <p>19 previously noted.</p> <p>20 THE WITNESS: So I didn't do this -- I</p> <p>21 didn't have any data. So I didn't do that at</p> <p>22 the state level, but I expect if I had the</p> <p>23 data, this would be limited by state law,</p> <p>24 according to instructions from counsel for the</p> <p>25 jury.</p>
<p style="text-align: right;">Page 123</p> <p>1 THE WITNESS: Okay. So, again, I'm</p> <p>2 not a lawyer. What I view is that the</p> <p>3 wholesalers took title of these products and</p> <p>4 then resold them into the retail class of</p> <p>5 trade. And it's the difference between what</p> <p>6 they acquire the drugs at -- for -- from when</p> <p>7 they purchase from the manufacturer to what</p> <p>8 they received from the retailers when they sold</p> <p>9 it into the market and the delta that is</p> <p>10 at-issue here.</p> <p>11 And later on in this section, I'm a</p> <p>12 little bit more specific about the profit that</p> <p>13 is made off -- through the wholesalers moving</p> <p>14 these products from A to B.</p> <p>15 BY MR. CAMPBELL:</p> <p>16 Q Okay. And we'll get to those formulas</p> <p>17 in just a couple of minutes, as you probably were</p> <p>18 expecting.</p> <p>19 Are you aware, when it comes to unjust</p> <p>20 enrichment, that there are different elements of</p> <p>21 proof from one state to another for an unjust</p> <p>22 enrichment claim?</p> <p>23 A I am generally aware of -- that states</p> <p>24 have different rules for unjust enrichment.</p> <p>25 Q And same for the proper measure of</p>	<p style="text-align: right;">Page 125</p> <p>1 THE COURT REPORTER: For what?</p> <p>2 THE WITNESS: For the jury. From</p> <p>3 instruction of counsel, the court or the jury.</p> <p>4 My -- my method is flexible to accommodate</p> <p>5 those state-specific rules.</p> <p>6 BY MR. CAMPBELL:</p> <p>7 Q Have you been given any descriptions</p> <p>8 of those differences in a law from one state to</p> <p>9 another so far?</p> <p>10 MR. HONIK: Note my objection to the</p> <p>11 extent it may invade the attorney work product</p> <p>12 privilege and other confidentiality privileges.</p> <p>13 But with that and without waiver of</p> <p>14 those objections, I'll allow her to answer.</p> <p>15 THE WITNESS: Again, I didn't have any</p> <p>16 data to do this calculation mechanically, so it</p> <p>17 wasn't really -- it wasn't a detail that I</p> <p>18 focused on.</p> <p>19 BY MR. CAMPBELL:</p> <p>20 Q When you say the detail that you were</p> <p>21 focused on, you mean a difference between one state</p> <p>22 versus another state and how the damages are</p> <p>23 calculated for unjust enrichment?</p> <p>24 A No. I mean by that, that I didn't</p> <p>25 mechanically calculate anything for wholesalers.</p>

<p style="text-align: right;">Page 126</p> <p>1 And so to the extent that unjust enrichment as</p> <p>2 applied to the wholesalers in this matter for these</p> <p>3 at-issue drugs might differ, I didn't do anything</p> <p>4 with that information because I had nothing to do.</p> <p>5 I don't have the data to do that based on the state.</p> <p>6 That's kind of a different part of the calculation</p> <p>7 even for what I did for retailers or for defendants</p> <p>8 in the different theories of liability.</p> <p>9 Q Can you tell us now how you would</p> <p>10 account in you formula for those differences from</p> <p>11 one state to another, or is that something that you</p> <p>12 would reserve for later?</p> <p>13 MR. HONIK: Note my objection to the</p> <p>14 extent it calls for a legal conclusion and/or</p> <p>15 instruction from judge, jury or counsel.</p> <p>16 You may answer.</p> <p>17 THE WITNESS: Thank you.</p> <p>18 Honestly, I think of it as a</p> <p>19 mechanical issue and one that I would wait on</p> <p>20 the instruction of counsel, the court or the</p> <p>21 jury to -- to do.</p> <p>22 BY MR. CAMPBELL:</p> <p>23 Q And the formula that you propose for</p> <p>24 the unjust enrichment damages is essentially</p> <p>25 profits. And that's defined as revenues minus cost</p>	<p style="text-align: right;">Page 128</p> <p>1 please. And I just want to clarify one thing.</p> <p>2 You see in this Paragraph 8,</p> <p>3 "Consequently, the appropriate measure of damages in</p> <p>4 this matter is the total amount paid by each</p> <p>5 plaintiff for the at-issue valsartan products</p> <p>6 manufactured and/or sold by the defendants."</p> <p>7 Do you see that paragraph?</p> <p>8 A Yes.</p> <p>9 Q That's not referring to the proper</p> <p>10 measure of damages for wholesalers, right?</p> <p>11 A Under the theory of unjust enrichment.</p> <p>12 THE COURT REPORTER: I'm sorry.</p> <p>13 THE WITNESS: Under the theory of</p> <p>14 unjust enrichment, correct.</p> <p>15 BY MR. CAMPBELL:</p> <p>16 Q So this -- what's described in</p> <p>17 Paragraph 8 refers to other defendants, not</p> <p>18 wholesalers?</p> <p>19 A That is correct.</p> <p>20 MR. HONIK: Object to form.</p> <p>21 I think -- Jamie, did you get the</p> <p>22 answer?</p> <p>23 THE COURT REPORTER: Yes.</p> <p>24 MR. HONIK: Thank you.</p> <p>25</p>
<p style="text-align: right;">Page 127</p> <p>1 as you have there at the beginning of Paragraph 81,</p> <p>2 right?</p> <p>3 A Correct.</p> <p>4 Q Why did you decide on that being the</p> <p>5 formula for unjust enrichment damages? Where did</p> <p>6 that come from?</p> <p>7 A Because, again, as I understand it,</p> <p>8 unjust enrichment is simply the amount of money made</p> <p>9 off of the transaction for moving drugs from one</p> <p>10 place to another net of cost.</p> <p>11 Q Did you rely on any written materials</p> <p>12 that told you that was the proper measure of damages</p> <p>13 for unjust enrichment?</p> <p>14 A I relied on counsel's instruction and</p> <p>15 kind of general understanding of what I know of</p> <p>16 unjust enrichment.</p> <p>17 Q So is counsel's instruction that the</p> <p>18 proper calculation of damages for unjust enrichment</p> <p>19 is revenues minus cost?</p> <p>20 MR. HONIK: Object to the form.</p> <p>21 THE WITNESS: Thank you.</p> <p>22 I should wait. Yes.</p> <p>23 BY MR. CAMPBELL:</p> <p>24 Q If you could -- actually, go back real</p> <p>25 quick to Paragraph 8 in the -- in your report,</p>	<p style="text-align: right;">Page 129</p> <p>1 BY MR. CAMPBELL:</p> <p>2 Q Okay. Back to your calculation of</p> <p>3 unjust enrichment damages, so we talked a lot</p> <p>4 yesterday about the value of the product or about</p> <p>5 the lack of value of the product in -- in your</p> <p>6 opinion. I don't want to get into any of that. I</p> <p>7 just want to ask one simple question about the value</p> <p>8 of the product.</p> <p>9 Do you base your calculation of unjust</p> <p>10 enrichment damages as to wholesalers on the basic</p> <p>11 premise that the products are worthless?</p> <p>12 THE COURT REPORTER: That the profits</p> <p>13 are worthless?</p> <p>14 MR. CAMPBELL: That the products.</p> <p>15 THE COURT REPORTER: Thank you.</p> <p>16 THE WITNESS: I am -- so in the</p> <p>17 wholesaler context, really, all that's at play</p> <p>18 here is the wholesalers moved at-issue products</p> <p>19 from one place to another. And therefore, they</p> <p>20 profited off of that movement.</p> <p>21 The full value of the products that</p> <p>22 they moved from one place to another is related</p> <p>23 to the price that they paid for them over every</p> <p>24 unit that they paid for them minus their cost</p> <p>25 of acquiring, storing, other --</p>

<p style="text-align: right;">Page 130</p> <p>1 THE COURT REPORTER: Other...</p> <p>2 THE WITNESS: Other offsets that they</p> <p>3 may -- may have experienced.</p> <p>4 So, really, it's just the full price</p> <p>5 that the wholesalers acquired those products at</p> <p>6 minus all of their costs that -- that is -- is</p> <p>7 related to my calculation here.</p> <p>8 BY MR. CAMPBELL:</p> <p>9 Q And so your calculation as to the</p> <p>10 wholesalers for unjust enrichment damages, it</p> <p>11 doesn't matter if the products are -- are worthless</p> <p>12 or not?</p> <p>13 MR. HONIK: Object to the form.</p> <p>14 THE WITNESS: For my purposes, I am --</p> <p>15 I was asked to -- so for my purposes, it's just</p> <p>16 the amount of money that the wholesalers made</p> <p>17 off moving these products from one place to</p> <p>18 another.</p> <p>19 BY MR. CAMPBELL:</p> <p>20 Q Okay.</p> <p>21 MR. CAMPBELL: And if the tech could</p> <p>22 go back to Paragraph 80, and next -- next page</p> <p>23 on Paragraph 80. Okay.</p> <p>24 BY MR. CAMPBELL:</p> <p>25 Q You see the sentence that starts off</p>	<p style="text-align: right;">Page 132</p> <p>1 THE WITNESS: I said correct. I said</p> <p>2 correct. And these are -- I'm sorry. My</p> <p>3 computer wants to reboot. Correct.</p> <p>4 I mean, these are major Fortune 500 or</p> <p>5 Fortune 1,000 companies. They have -- as you</p> <p>6 know, AmerisourceBergen and Cardinal and others</p> <p>7 have revenues, annual revenues, on the order of</p> <p>8 Costco. And these are huge public -- publicly</p> <p>9 traded companies. They must profit off their</p> <p>10 business, or they wouldn't report revenue that</p> <p>11 looks like that. But I have not been shown any</p> <p>12 data to assess exactly how much they -- these</p> <p>13 wholesalers made off of moving from point A to</p> <p>14 point B, the specific issues in this matter.</p> <p>15 THE COURT REPORTER: In what?</p> <p>16 THE WITNESS: The specific drugs in</p> <p>17 this matter.</p> <p>18 THE VIDEOGRAPHER: Counsel, I'm</p> <p>19 getting a lot of background noise. If we can</p> <p>20 just try to reduce that as best as we can.</p> <p>21 Thank you.</p> <p>22 BY MR. CAMPBELL:</p> <p>23 Q All right. And in the next couple of</p> <p>24 sentences in Paragraph 80, you talk about,</p> <p>25 "Wholesalers did not manufacture the products, nor</p>
<p style="text-align: right;">Page 131</p> <p>1 with, "Like the defendant retailers"? We don't have</p> <p>2 the first couple of words, but the first couple</p> <p>3 words highlighted here are "like the"?</p> <p>4 A Yes.</p> <p>5 Q Okay. "Like the defendant retailers,</p> <p>6 these companies profited from the distribution of</p> <p>7 the at-issue valsartan products to pharmacies and</p> <p>8 other entities."</p> <p>9 On what do you base that statement</p> <p>10 there, that these companies profited?</p> <p>11 A Right. So this is just the theory of</p> <p>12 unjust enrichment that as -- so just kind of as a</p> <p>13 general matter, we know that wholesalers move</p> <p>14 drug -- they take title of drugs. And then they</p> <p>15 move them to other purchasers, or they sell them to</p> <p>16 other purchasers. So it's just the difference</p> <p>17 between the -- the amount they sold and the amount</p> <p>18 that they gained that is of issue here.</p> <p>19 Q Okay. So this is the theory. It's</p> <p>20 not based on any actual records or documents that</p> <p>21 you've seen so far?</p> <p>22 MR. HONIK: Object to the form of the</p> <p>23 question.</p> <p>24 THE COURT REPORTER: I'm sorry, I</p> <p>25 didn't hear an answer.</p>	<p style="text-align: right;">Page 133</p> <p>1 did they sell the products to consumers and TPPs."</p> <p>2 And then you say, "Consequently, the</p> <p>3 data that could be used to calculate unjust</p> <p>4 enrichment damages for defendant wholesalers differs</p> <p>5 from that of the defendant retailers described</p> <p>6 above."</p> <p>7 Do you see that sentence?</p> <p>8 A Yes, that's what it says.</p> <p>9 Q Okay. In what ways does the data that</p> <p>10 could be used to calculate unjust enrichment damages</p> <p>11 for wholesalers differ from the retailers?</p> <p>12 A So, again, the -- the wholesalers</p> <p>13 purchased these products at one price and -- in</p> <p>14 aggregate and then sell them at another. It's just</p> <p>15 the delta that matters.</p> <p>16 And the -- the purchase price is going</p> <p>17 to be reported in data just like -- and the products</p> <p>18 themselves, the name of the manufacturers, the lot,</p> <p>19 the batch, the NDC code, all of that should be</p> <p>20 preserved in this data. But the actual cost of</p> <p>21 sales will be -- will be different.</p> <p>22 Q And have you ever seen that sort of</p> <p>23 data for -- for wholesalers other than -- I think</p> <p>24 you mentioned the screen share earlier in the call.</p> <p>25 But have you otherwise ever seen that sort of data</p>

<p style="text-align: right;">Page 134</p> <p>1 for wholesalers?</p> <p>2 A Yeah. I have seen that data,</p> <p>3 and -- under Track and Trace and earlier versions of</p> <p>4 Track and Trace that are maintained by the states</p> <p>5 through the EPedigree system. My understanding is</p> <p>6 that wholesalers keep track of that data down to the</p> <p>7 unit penny.</p> <p>8 Q And you're referring to the cost of</p> <p>9 the -- you said the cost of the sales earlier. So</p> <p>10 you mean the sale to the retailer?</p> <p>11 A Yeah. And -- and the price that the</p> <p>12 wholesalers are paying to the manufacturers as well.</p> <p>13 So they -- they know how much they're purchasing and</p> <p>14 at what price for what. And they know how much</p> <p>15 they're selling for, by whom, for what, down to the</p> <p>16 retailer level as well.</p> <p>17 Q And I just want to make sure I</p> <p>18 understand. On what is that based, your</p> <p>19 understanding that they -- they know all those</p> <p>20 things?</p> <p>21 A Again -- well, so under Track and</p> <p>22 Trace, they are required -- wholesalers are required</p> <p>23 to keep that information at that level of this</p> <p>24 aggregation, at the NDC manufacturer level and the</p> <p>25 unit level. And then states, on top of Track and</p>	<p style="text-align: right;">Page 136</p> <p>1 enter the retail class of trade in the U.S. has a</p> <p>2 barcode and is -- is traced through the entire</p> <p>3 system. So by definition, if the manufacturers are</p> <p>4 entering these products into the retail class of</p> <p>5 trade, then downstream members of the supply chain,</p> <p>6 whether it be wholesalers or retailers, are required</p> <p>7 to keep track of that product at the barcode level,</p> <p>8 which will contain information about the product,</p> <p>9 the -- the unit and -- and the manufacturers.</p> <p>10 Q What about elements of price? Does it</p> <p>11 track the elements of price?</p> <p>12 A What do you mean by "elements of</p> <p>13 price"?</p> <p>14 Q Well, the amounts received. Let's</p> <p>15 start, first of all, with the revenues.</p> <p>16 A Sure.</p> <p>17 Q Okay? Which is -- let's go to that</p> <p>18 part of your formula about the revenues, and that's</p> <p>19 in Paragraph 82.</p> <p>20 A Yeah.</p> <p>21 Q Okay.</p> <p>22 A I have that.</p> <p>23 Q All right. And it -- it says</p> <p>24 wholesaler revenue can be expressed in Formula 10 as</p> <p>25 Qdt multiplied by PPUdt. Do you see that?</p>
<p style="text-align: right;">Page 135</p> <p>1 Trace, have EPedigree systems that require all</p> <p>2 members of the supply chain in the United States to</p> <p>3 maintain units sold or purchased, which types of</p> <p>4 drugs by which types of manufacturers to ensure that</p> <p>5 they are not counterfeit.</p> <p>6 Q Have you ever had any specific</p> <p>7 conversations with someone who works for a</p> <p>8 wholesaler about the input needed to calculate</p> <p>9 profits on any given transaction or -- or drug?</p> <p>10 A I mean -- this field is awash in data,</p> <p>11 and I am aware that wholesalers are keeping track of</p> <p>12 their unit costs and their unit --</p> <p>13 THE COURT REPORTER: Their unit what?</p> <p>14 THE WITNESS: Or their revenues</p> <p>15 for -- for each transaction that they are going</p> <p>16 through every single day. Again, 11 million</p> <p>17 prescriptions units a day are going through the</p> <p>18 wholesalers in the U.S. market.</p> <p>19 BY MR. CAMPBELL:</p> <p>20 Q Have you ever had any specific</p> <p>21 conversations with any of the wholesalers in this</p> <p>22 case, employees of the wholesalers in this case,</p> <p>23 that they are keeping that sort of data regarding</p> <p>24 the at-issue valsartan?</p> <p>25 A Again, any product that is allowed to</p>	<p style="text-align: right;">Page 137</p> <p>1 A Yes.</p> <p>2 Q Did you consider any other inputs in</p> <p>3 determining revenue here for -- with respect to</p> <p>4 wholesalers?</p> <p>5 A Like what?</p> <p>6 Q Well, that's what I'm asking you. I'm</p> <p>7 asking you.</p> <p>8 A I don't -- I don't understand.</p> <p>9 Q Sure.</p> <p>10 You have QDt --</p> <p>11 A Right.</p> <p>12 Q -- and PPUdt as the two inputs that</p> <p>13 you multiply together to get revenue, right?</p> <p>14 A Right.</p> <p>15 Q Okay. Did you consider any other</p> <p>16 things to multiply or include in this part of the</p> <p>17 formula that you decided should not be included?</p> <p>18 A This is a general formula. So it is</p> <p>19 inclusive of the aggregate units and the transaction</p> <p>20 prices for these units. Transaction prices could</p> <p>21 be -- are probably expressed in aggregate over</p> <p>22 products. And there may be a difference between</p> <p>23 gross prices paid and net prices paid. There might</p> <p>24 be offsets, return of goods, et cetera, that</p> <p>25 are -- that are part of either the revenue or part</p>

<p style="text-align: right;">Page 138</p> <p>1 of the cost.</p> <p>2 Q And how does that factor into your</p> <p>3 formula here?</p> <p>4 A It's inclusive.</p> <p>5 Q In what way?</p> <p>6 A And you can -- well, you can see</p> <p>7 in -- in Footnote 75, when calculating profit,</p> <p>8 offset may be removed from gross profit, so the jury</p> <p>9 or court find these to be reasonable deductions.</p> <p>10 These additional costs can be easily included.</p> <p>11 THE COURT REPORTER: Can be easily...</p> <p>12 THE WITNESS: Included.</p> <p>13 BY MR. CAMPBELL:</p> <p>14 Q So your Paragraph 75 there, is that</p> <p>15 referring to -- for example, if we start with inputs</p> <p>16 to revenue, does that include rebates?</p> <p>17 A It could. It could, yes. So there's</p> <p>18 a gross price, and then there's returned goods.</p> <p>19 There's rebates that might be paid on aggregate</p> <p>20 purchased products or sold products. All of those</p> <p>21 would be considered, not gross revenue or not gross</p> <p>22 prices, but net prices and could be a part of those</p> <p>23 calculations if counsel or the court or the jury</p> <p>24 find that they should be included.</p> <p>25 Q Do you have an opinion on whether they</p>	<p style="text-align: right;">Page 140</p> <p>1 those inclusions if the court or the jury or</p> <p>2 counsel determined they should be included.</p> <p>3 BY MR. CAMPBELL:</p> <p>4 Q Hypothetically, if a wholesaler came</p> <p>5 to you and asked you to help them calculate profits</p> <p>6 on a particular set of drugs outside the context of</p> <p>7 any litigation, would you include rebates in that</p> <p>8 calculation of profits?</p> <p>9 MR. HONIK: Note my objection,</p> <p>10 improper hypothetical.</p> <p>11 THE WITNESS: Okay. I think we've all</p> <p>12 established how much I love hypothetical</p> <p>13 questions, and I think the answer to this one</p> <p>14 is just, it depends. It depends on the</p> <p>15 context.</p> <p>16 BY MR. CAMPBELL:</p> <p>17 Q So in some context, you would include</p> <p>18 rebates?</p> <p>19 THE COURT REPORTER: I'm sorry, can</p> <p>20 you repeat that question?</p> <p>21 MR. CAMPBELL: Sure.</p> <p>22 BY MR. CAMPBELL:</p> <p>23 Q In some context, you would include</p> <p>24 rebates in the calculation of revenues?</p> <p>25 MR. HONIK: Object to the form of the</p>
<p style="text-align: right;">Page 139</p> <p>1 should be included?</p> <p>2 MR. HONIK: Note my objection to the</p> <p>3 extent it calls for a legal conclusion.</p> <p>4 THE WITNESS: My method and the</p> <p>5 formula that's listed here is -- is general.</p> <p>6 BY MR. CAMPBELL:</p> <p>7 Q And I'm not asking you in a legal</p> <p>8 opinion. I'm asking you as the expert health</p> <p>9 economist here. If you were calculating profits for</p> <p>10 a particular set of drugs for a wholesaler, would</p> <p>11 you factor in rebates?</p> <p>12 MR. HONIK: Note my objection. The</p> <p>13 ultimate answer to the question requires,</p> <p>14 respectfully, a legal determination, one that's</p> <p>15 beyond the scope.</p> <p>16 But with that, she can answer the</p> <p>17 question.</p> <p>18 THE WITNESS: Thank you.</p> <p>19 So, again, I'm not a lawyer. I'm an</p> <p>20 economist. I would say if I didn't think that</p> <p>21 they -- that those factors should be</p> <p>22 considered, I would not have dropped the</p> <p>23 footnote that I did. We were just talking</p> <p>24 about Footnote 75. And, again, the method that</p> <p>25 is proposed is -- is flexible to accommodate</p>	<p style="text-align: right;">Page 141</p> <p>1 question.</p> <p>2 THE WITNESS: And you mean profits?</p> <p>3 BY MR. CAMPBELL:</p> <p>4 Q Profits, sure.</p> <p>5 A Possibly.</p> <p>6 Q And with respect to rebates, do you</p> <p>7 understand that different customers have different</p> <p>8 rebate structures? I should say different</p> <p>9 wholesaler customers have different rebate</p> <p>10 structures?</p> <p>11 A What do you mean by "customers"?</p> <p>12 Q Sure.</p> <p>13 So one particular customer for a</p> <p>14 wholesaler might have a rebate structure that has</p> <p>15 these numbers or these incentives. And another</p> <p>16 customer for that same wholesaler might have a</p> <p>17 totally different rebate structure.</p> <p>18 MR. HONIK: Object to the form.</p> <p>19 THE WITNESS: I think I'm asking a</p> <p>20 much more basic question, which is who is the</p> <p>21 customer.</p> <p>22 BY MR. CAMPBELL:</p> <p>23 Q It doesn't matter. Let's say --</p> <p>24 A Customer of whom?</p> <p>25 THE COURT REPORTER: I'm sorry?</p>

<p style="text-align: right;">Page 142</p> <p>1 MR. CAMPBELL: I'm sorry.</p> <p>2 THE WITNESS: Let's start from the</p> <p>3 beginning. Customer of whom?</p> <p>4 BY MR. CAMPBELL:</p> <p>5 Q Yeah. A wholesaler customer.</p> <p>6 A Okay. So is that the manufacturer?</p> <p>7 So remember, wholesalers operate a two-sided market.</p> <p>8 So they are -- they have manufacturers that they are</p> <p>9 purchasing products from. That is one type of</p> <p>10 customer.</p> <p>11 And then they are selling downstream</p> <p>12 to other customers that are retail pharmacies and</p> <p>13 other members of the supply chain. So that's</p> <p>14 another type of customer. So I'm asking you which</p> <p>15 customer.</p> <p>16 Q Okay. So now I'm in the category of</p> <p>17 revenues, so I'm talking about the downstream</p> <p>18 customers.</p> <p>19 A Okay. Great.</p> <p>20 Q Okay. The -- the retail pharmacies,</p> <p>21 pick any two that you want to for the wholesalers.</p> <p>22 Do you understand that different customers,</p> <p>23 different retail or pharmacy customers, might have</p> <p>24 different rebate structures?</p> <p>25 A So as a general matter, I understand</p>	<p style="text-align: right;">Page 144</p> <p>1 the other wholesalers at-issue here, they are</p> <p>2 massive corporations. Again, they have annual</p> <p>3 revenues larger than Costco. So they have --</p> <p>4 they hold very significant market power over</p> <p>5 their downstream retail customers.</p> <p>6 So in that setting, as a general</p> <p>7 matter, the entity that holds the more</p> <p>8 significant market power gets to dictate the</p> <p>9 terms of the contract. And so I'm assuming</p> <p>10 that AmerisourceBergen dictates the terms of</p> <p>11 the contract, and I expect those terms of the</p> <p>12 contract in a given period of time to not</p> <p>13 differ very significantly between retail</p> <p>14 customer or retail pharmacy -- between retail</p> <p>15 pharmacy and the retail pharmacy.</p> <p>16 Might there be slight deviations</p> <p>17 between them? Sure. But the general content</p> <p>18 is going to be driven by the entity that holds</p> <p>19 the market power.</p> <p>20 BY MR. CAMPBELL:</p> <p>21 Q So you agree that --</p> <p>22 A Which is the wholesaler.</p> <p>23 Q So you agree that there might be</p> <p>24 slight variations in, for example, the amount of</p> <p>25 rebates given to one retailer versus another?</p>
<p style="text-align: right;">Page 143</p> <p>1 that these contracts may include rebates that are</p> <p>2 generally paid in aggregate and are contracted to an</p> <p>3 advance of any specific transaction. So they're</p> <p>4 contracts that cover a period prospectively.</p> <p>5 If -- whether they differ materially</p> <p>6 from each other, I -- I think that they may differ</p> <p>7 in time. In other words, the contracting that</p> <p>8 occurs in 2020 as a general rule looks different</p> <p>9 than the contracting that might have occurred in</p> <p>10 2012. But if a differ -- I mean, AmerisourceBergen</p> <p>11 and Cardinal, they're really major players in this</p> <p>12 market. And they have significant market power. So</p> <p>13 I'm assuming that they have a pretty uniform</p> <p>14 contract that they are -- they have for signing with</p> <p>15 their downstream customers, the retailers.</p> <p>16 Q So your assumption is that, for</p> <p>17 example, for Cardinal Health, its contracts are</p> <p>18 going to look the same with respect to rebates with</p> <p>19 its retailer customers, no matter who the retailer</p> <p>20 customer is?</p> <p>21 MR. HONIK: Object to the form.</p> <p>22 That's not her testimony.</p> <p>23 THE WITNESS: No -- yeah, I think</p> <p>24 you're mischaracterizing my testimony. What</p> <p>25 I'm saying is that AmerisourceBergen, Cardinal,</p>	<p style="text-align: right;">Page 145</p> <p>1 A If they exist at all, right? I mean,</p> <p>2 there could be just cost contracts all together. It</p> <p>3 probably depends on the year and the products.</p> <p>4 Q And beyond just rebates, there might</p> <p>5 be other terms in the contracts that might differ</p> <p>6 from one retailer customer to another?</p> <p>7 MR. HONIK: Object to the form, calls</p> <p>8 for a legal conclusion.</p> <p>9 THE WITNESS: Again, I haven't really</p> <p>10 thought about that in this matter that much.</p> <p>11 What I would say is, the contracts probably</p> <p>12 dictate a variety of different terms that are</p> <p>13 general -- that are general, amount sold at</p> <p>14 prices over which types of products in a given</p> <p>15 time period, what to do about charge backs or</p> <p>16 spoiled goods, what to do about whether there's</p> <p>17 aggregate volume discounts for purchasing a</p> <p>18 very large quantity of their certain products.</p> <p>19 There might also be wholesale rebates</p> <p>20 for -- in aggregate after the products have</p> <p>21 already been sold into the supply chain and</p> <p>22 maybe even to customers that are freed up</p> <p>23 later. Are all likely part of the contracts</p> <p>24 and might differ over time.</p> <p>25</p>

<p style="text-align: right;">Page 146</p> <p>1 BY MR. CAMPBELL:</p> <p>2 Q Did you review any wholesaler and</p> <p>3 retailer contracts produced in this litigation?</p> <p>4 A No, not in this matter, but I have</p> <p>5 seen contracts between wholesalers and retail</p> <p>6 pharmacies in the course of business.</p> <p>7 Q Any related to the products at-issue</p> <p>8 in this litigation?</p> <p>9 A No. But, again, these are</p> <p>10 really -- these are, you know, cheap generic drugs.</p> <p>11 The -- and so I don't expect them to differ that</p> <p>12 much or to be special in any way. Where I have seen</p> <p>13 carve out or special considerations are for products</p> <p>14 that have very special types of handling or shelf</p> <p>15 life.</p> <p>16 Q And going to your formula for cost,</p> <p>17 which is at the bottom of Page 33, it's Formula 11.</p> <p>18 Well, one thing I wanted to --</p> <p>19 A Hold on. Hold on. Let me just get</p> <p>20 there.</p> <p>21 Q One thing before I continue on that,</p> <p>22 one of the elements of your formulas is -- is the</p> <p>23 concept of unit, correct?</p> <p>24 A Yes.</p> <p>25 Q All right. What is your definition</p>	<p style="text-align: right;">Page 148</p> <p>1 Q Okay. So let me go to your formula</p> <p>2 for cost. For the formula for cost, Formula 11, I</p> <p>3 guess it is. It continues on to the top of the next</p> <p>4 page. In this part of your formula for cost, did</p> <p>5 you consider including charge backs?</p> <p>6 A Again, this is what I mean by,</p> <p>7 in -- in that Footnote 75, that there could be</p> <p>8 offsets to profit that could be considered, either</p> <p>9 in the cost side or in the revenue side.</p> <p>10 I think I have already mentioned</p> <p>11 charge backs as being an offset in the -- in our</p> <p>12 earlier conversation. They may be related here or</p> <p>13 important.</p> <p>14 Q And you would say the same thing for</p> <p>15 rebates?</p> <p>16 A Again, I think of volume discounted as</p> <p>17 being a more relevant term, but there might also be</p> <p>18 rebates there.</p> <p>19 Q You mentioned discounts. You're</p> <p>20 aware --</p> <p>21 A Wait a minute. I'm sorry. Just a</p> <p>22 minute. Just to finish my thought.</p> <p>23 Again, I didn't do this mechanically.</p> <p>24 I didn't have any data to do that, and so my method</p> <p>25 that's being proposed here is general. And it's</p>
<p style="text-align: right;">Page 147</p> <p>1 for -- for unit here in this formula for</p> <p>2 wholesalers?</p> <p>3 A Yeah, it's -- it's quantity. It's</p> <p>4 quantity, and usually at the wholesaler level,</p> <p>5 they'll be -- it will be bottles or packages of</p> <p>6 pills. But it might also be aggregated over larger</p> <p>7 units, so, like, multiple pill packs or multiple</p> <p>8 boxes of products.</p> <p>9 Q So a unit can be a different size,</p> <p>10 basically?</p> <p>11 A Units can be different sizes, and the</p> <p>12 size and the aggregate amounts contained in those</p> <p>13 units are things that the wholesaler knows and keeps</p> <p>14 track of. It's part of the requirements of Track</p> <p>15 and Trace and also the EPedigree system that I</p> <p>16 mentioned earlier.</p> <p>17 Q Does your formula account for the</p> <p>18 differences in sizes between units?</p> <p>19 A Yes. And if I -- again, this</p> <p>20 is -- this is a theoretical exercise. I have no</p> <p>21 data. But I tend to be very anal about units sizes,</p> <p>22 and so this would be done at a unit that may -- at</p> <p>23 the most disaggregated unit that was appropriate.</p> <p>24 And usually units for cost would match the units for</p> <p>25 revenues, if I was doing this with data.</p>	<p style="text-align: right;">Page 149</p> <p>1 really a different phase of the case, either upon</p> <p>2 the instruction of counsel and upon of the</p> <p>3 instruction from the court or jury, that those type</p> <p>4 of offsets, if they exist, either for cost or for</p> <p>5 revenue.</p> <p>6 Q But you would defer to the court or</p> <p>7 the jury to decide whether those sorts of things</p> <p>8 should be included?</p> <p>9 A Correct.</p> <p>10 Q And with the same -- you mentioned</p> <p>11 discounts. Would the same thing apply, for example,</p> <p>12 on the cost side, logistics fees or service fees?</p> <p>13 A For unjust enrichment calculations,</p> <p>14 yes, that -- those also could potentially be</p> <p>15 accounted for. My method is flexible to account for</p> <p>16 them, again, upon the instruction of counsel, the</p> <p>17 court or the jury.</p> <p>18 Q What about non-product-related costs,</p> <p>19 for example, wholesaler overhead or employee costs</p> <p>20 or IT costs, those sorts of things? Are those also</p> <p>21 included in the offsets that you would defer to</p> <p>22 whether the court or the jury says they should be</p> <p>23 counted?</p> <p>24 A I think of all of these things -- so</p> <p>25 to the extent that they're all related to cost of</p>

<p style="text-align: right;">Page 150</p> <p>1 goods, they would be related. Usually, I've seen 2 cost of goods break out those type of costs 3 separately. 4 Q Employee costs, information technology 5 costs, store costs, those sort of things? 6 A I mean there's -- they're -- they're 7 huge. They're so big. You know, they're their own 8 separate line items. They're -- they have their own 9 department that -- that accrues those costs and 10 accounts for those costs and that keeps track of 11 those costs and reports them to their shareholders. 12 I've -- I've used those as different cost of goods 13 for the unit being moved from one place to another. 14 Usually, that -- in gap accounting, they're 15 accounted for separately. 16 Q Okay. And then on the other inputs 17 for the costs, of all the things that you said, 18 maybe offsets, and you would defer to the court or 19 the jury to decide whether they're -- they're 20 counted. Those also will, or could, vary from 21 manufacturer to manufacturer depending on the 22 contract, right? 23 A Okay. So I think we're switching. So 24 I think what you mean is that -- so now the customer 25 is the upstream customer to the wholesaler, right?</p>	<p style="text-align: right;">Page 152</p> <p>1 secrets in my general understanding of -- of how 2 this world works. I -- I wish I could see them, but 3 I haven't seen them in -- in -- in this matter. And 4 I have asked lots of questions of my wholesaler 5 friends about, kind of, generally how these work, 6 but I have never seen a contract. 7 Q And do you agree that wholesalers 8 typically negotiate with the manufacturers when 9 they're entering into one of these contracts over a 10 bundle of goods and not with any one particular type 11 of product? 12 A I mean, it depends on who the 13 wholesale -- I mean, it depends on who the 14 manufacturer is, right, and what the products are. 15 But -- so I do not -- I don't know the specifics of 16 the contracts between the wholesaler and the 17 specific manufacturers in this case. 18 Q Okay. And I think you already 19 mentioned when you talked about the concept of time, 20 but it's your understanding that the contracts, both 21 types of contracts, the contracts between the 22 wholesalers and the manufacturers, and then the 23 wholesalers and the retail pharmacies, those 24 contracts can change over time, correct? 25 A Yes. Typically, wholesalers would</p>
<p style="text-align: right;">Page 151</p> <p>1 It's the manufacturer? 2 Q That's right? 3 A Is that right? 4 Q Yes. 5 A Okay. So, again, same general gist, 6 which is wholesalers are method in terms of revenue 7 and in terms of market share relative to each 8 individual pharmaceutical company that they're 9 dealing with. And so for the contract between 10 AmerisourceBergen, for example, and any specific 11 small generic manufacturer, the entity that holds 12 the bargaining power is the wholesaler, not 13 generally the -- the manufacturer. 14 So, again, I expect, just as a manner 15 of management, that the wholesalers here can dictate 16 the terms of purchase to these upstream 17 manufacturers, and they might differ a little bit by 18 time, by type of product, et cetera. But I don't 19 anticipate that within time and for a particular 20 type of product, there -- there to be very 21 significant differences. 22 Q Did you review any of the contracts 23 between the wholesalers and the manufacturers that 24 were produced in this case? 25 A No. Those are very closely held</p>	<p style="text-align: right;">Page 153</p> <p>1 contract upstream and downstream prospectively, and 2 those contracts will have a term. So they'll be 3 for -- prospectively, for a year, two years. 4 Q And the terms may vary from 5 manufacturer to manufacturer or from retail pharmacy 6 to retail pharmacy? 7 MR. HONIK: Objection, asked and 8 answered. 9 THE WITNESS: So, again, you're -- if 10 you're a Fortune 1,000 company, such as these 11 in the U.S., they tend to be pretty routinized, 12 and also it's important to be routinized for 13 the principles of gap reporting for 14 shareholders. Again, these are public 15 companies. So -- 16 THE COURT REPORTER: They're to be 17 routinized? 18 THE WITNESS: Routinized. 19 THE COURT REPORTER: Routinized? 20 THE WITNESS: Yes. 21 THE COURT REPORTER: Okay. 22 THE WITNESS: Routinized. 23 But as a general matter, my 24 understanding is that the contracts are for a 25 year or two, both upstream and downstream.</p>

<p style="text-align: right;">Page 154</p> <p>1 MR. HONIK: And let me -- let me just</p> <p>2 note that it's the 1 o'clock hour. I think we</p> <p>3 had a hard stop at this time, but to the extent</p> <p>4 y'all need more time, I think Dr. Conti will</p> <p>5 make herself available at 4 p.m.</p> <p>6 THE WITNESS: Yeah, I apologize. I'm</p> <p>7 actually late to meet my Dean. That's not a</p> <p>8 good -- that's not a good look for me.</p> <p>9 MR. HONIK: Let's go off the record</p> <p>10 and release the witness for now, and counsel</p> <p>11 can confer.</p> <p>12 THE VIDEOGRAPHER: The time is 1 p.m.</p> <p>13 This ends Media Unit Number 3. We're going off</p> <p>14 the record.</p> <p>15 (Whereupon, a break was taken from</p> <p>16 1 p.m. to 4 p.m.)</p> <p>17 THE VIDEOGRAPHER: The time is 4:03.</p> <p>18 This begins Media Unit Number 4. We're back on</p> <p>19 the record.</p> <p>20 BY MR. ABRAHAM:</p> <p>21 Q Good afternoon, Dr. Conti.</p> <p>22 A Good afternoon.</p> <p>23 Q My name is Eric Abraham -- Hetero Labs</p> <p>24 and Hetero Drugs. Can you hear me? You're</p> <p>25 making --</p>	<p style="text-align: right;">Page 156</p> <p>1 a few questions for you.</p> <p>2 Do you still have your expert report</p> <p>3 in front of you?</p> <p>4 A I do.</p> <p>5 Q Okay. I'd would like to draw your</p> <p>6 attention, please, to Paragraph 60.</p> <p>7 A Just give me one second.</p> <p>8 Q It's on Page 23. Do you have it?</p> <p>9 A Just one minute.</p> <p>10 Q Okay.</p> <p>11 A Yeah. Okay. I'm there.</p> <p>12 Q Okay. And this -- in this, you</p> <p>13 express the formula or the methodology for</p> <p>14 calculating liability damages as -- effectively,</p> <p>15 quantity as of the date and time for a particular</p> <p>16 product over time period, times the price for that</p> <p>17 product over the same time period; is that correct?</p> <p>18 A Correct.</p> <p>19 Q Okay. And I believe that you</p> <p>20 testified earlier today that, for Hetero, you</p> <p>21 confined your damages analysis to prescriptions that</p> <p>22 were filled between May and August of 2018, correct?</p> <p>23 A That's correct.</p> <p>24 Q Okay. And that's consistent with</p> <p>25 Footnote 67 of your report, right?</p>
<p style="text-align: right;">Page 155</p> <p>1 A No, I can't -- you just cut out again.</p> <p>2 MR. HONIK: You briefly cut out, Eric.</p> <p>3 Keep going. Let's see how it goes. We'll let</p> <p>4 you know if it's a problem.</p> <p>5 BY MR. ABRAHAM:</p> <p>6 Q Okay. Let's make sure we get the</p> <p>7 important point. I represent Hetero Drugs and</p> <p>8 Hetero Labs, and I'm going to be taking just a few</p> <p>9 additional questions today. All right?</p> <p>10 Do you still have your report in front</p> <p>11 of you?</p> <p>12 THE WITNESS: I'm sorry. Does</p> <p>13 everyone hear the background noise? It's very</p> <p>14 significant. There's -- it's like a computer</p> <p>15 noise.</p> <p>16 THE VIDEOGRAPHER: The time is 4:04.</p> <p>17 We're going off the record.</p> <p>18 (Whereupon, a discussion was held off</p> <p>19 the record.)</p> <p>20 THE VIDEOGRAPHER: The time is 4:05.</p> <p>21 We're back on the record.</p> <p>22 BY MR. ABRAHAM:</p> <p>23 Q Good afternoon, Dr. Conti. My name is</p> <p>24 Eric Abraham from law firm Hill Wallack, and I</p> <p>25 represent Hetero Labs and Hetero Drugs. I have just</p>	<p style="text-align: right;">Page 157</p> <p>1 A Just give me one second. I have to</p> <p>2 double check. Yes, that's correct.</p> <p>3 Q Did you do any investigation to</p> <p>4 determine whether any of Hetero's valsartan was sold</p> <p>5 within that timeframe, May through August of 2018,</p> <p>6 that did not contain an alleged nitrosamine</p> <p>7 impurity?</p> <p>8 A I did not, and that's because my</p> <p>9 analysis is prospective and under the assumption</p> <p>10 that consumers and third-party payors could not tell</p> <p>11 whether a product was contaminated or not -- or</p> <p>12 could not tell whether a product was contaminated or</p> <p>13 not with the nitrosamines and other potential</p> <p>14 products.</p> <p>15 Q So is it fair to say that you assumed,</p> <p>16 for purposes of your analysis, that if a</p> <p>17 prescription was filled within that timeframe, May</p> <p>18 through August 2018, the valsartan contained the</p> <p>19 nitrosamine impurity?</p> <p>20 MR. HONIK: Object to form.</p> <p>21 THE WITNESS: Right. So, again, and</p> <p>22 as I write this -- I write in my report, there</p> <p>23 is fundamental asymmetric information in this</p> <p>24 market. In other words, while the manufacturer</p> <p>25 might know the extent of the contamination of</p>

<p style="text-align: right;">Page 158</p> <p>1 their products, consumers nor third-party</p> <p>2 payors knew of at the time that they were</p> <p>3 making --</p> <p>4 THE COURT REPORTER: That they were</p> <p>5 making...</p> <p>6 THE WITNESS: At the time that they</p> <p>7 were making those purchases. And therefore,</p> <p>8 because my perspective is prospective, I'm</p> <p>9 doing the analysis from the -- from the</p> <p>10 perspective that -- of them and their</p> <p>11 asymmetric information. I am counting all</p> <p>12 products that were available for sale and</p> <p>13 ultimately sold in the U.S. market. That does</p> <p>14 not count -- that does not take into account</p> <p>15 that there may have been different levels of</p> <p>16 contamination that the manufacturer might have</p> <p>17 known about their own product.</p> <p>18 BY MR. ABRAHAM:</p> <p>19 Q Okay. So to the extent that there may</p> <p>20 have been valsartan manufactured by Hetero without</p> <p>21 the impurity that was still sitting on the shelf at</p> <p>22 the pharmacy in the May to August timeframe, those</p> <p>23 sales would be included with -- in your damages</p> <p>24 analysis, correct?</p> <p>25 A Correct. At --</p>	<p style="text-align: right;">Page 160</p> <p>1 both end-payor and consumer damages, attributable to</p> <p>2 the Hetero Labs. Do you see that?</p> <p>3 A I do.</p> <p>4 Q Does that calculation follow the</p> <p>5 formula that we talked about a few moments ago? It</p> <p>6 was on Paragraph 60 of your report, in other words,</p> <p>7 quantity times price?</p> <p>8 A Quantity times price, correct of all</p> <p>9 products in that time period that are relevant for</p> <p>10 that specific set of NDCs.</p> <p>11 Q Tell me what the quantity of pills you</p> <p>12 used was for the Hetero Labs end-payor damages</p> <p>13 calculation that resulted in roughly [REDACTED] in</p> <p>14 damages?</p> <p>15 A Sure. Sales --</p> <p>16 Q No, just a number. What was the</p> <p>17 number?</p> <p>18 A So sales of the product as recorded in</p> <p>19 the IQVIA data in the relevant time period among</p> <p>20 consumers that were -- among payors -- among</p> <p>21 prescriptions that were dispensed and paid for by</p> <p>22 third-party payors.</p> <p>23 Q I may not have been clear. I would</p> <p>24 like to know what the number was that you used for</p> <p>25 quantity within your equation.</p>
<p style="text-align: right;">Page 159</p> <p>1 Q I --</p> <p>2 A Wait. At this point in time --</p> <p>3 Q Right. I have very limited time,</p> <p>4 Dr. Conti.</p> <p>5 A No. No. No. I understand. I just</p> <p>6 need to -- but it's --</p> <p>7 Q You've answered my question.</p> <p>8 MR. HONIK: No, she hasn't. She</p> <p>9 hasn't finished her answer.</p> <p>10 THE WITNESS: So, again, from my</p> <p>11 perspective, at this point in time, my</p> <p>12 assignment was to think about damages in a</p> <p>13 prospective way from the consumer and</p> <p>14 third-party payors' perspective. They did not</p> <p>15 know whether the products that were being sold</p> <p>16 and consumed by themselves or paid for by</p> <p>17 themselves were contaminated or not, even if</p> <p>18 the manufacturer did know.</p> <p>19 BY MR. ABRAHAM:</p> <p>20 Q Can you please turn to Table 1 of your</p> <p>21 report?</p> <p>22 A Yes.</p> <p>23 Q It's on Page 31.</p> <p>24 A Yeah.</p> <p>25 Q And you see you have a line here for</p>	<p style="text-align: right;">Page 161</p> <p>1 A So I don't have it in my report, but</p> <p>2 it is easily discernable in the data that I have.</p> <p>3 I'm more than happy to provide that to you.</p> <p>4 Q Please do. I'll ask your counsel to</p> <p>5 provide me with that number.</p> <p>6 And what was the price that you used</p> <p>7 to calculate the [REDACTED] number for end-payor</p> <p>8 damages?</p> <p>9 A Same -- same answer, it was the price</p> <p>10 that was paid by end-payors recorded in IQVIA data,</p> <p>11 according to the inclusion/exclusion criteria for</p> <p>12 the specific products that are Hetero -- that are</p> <p>13 assigned to Hetero Labs.</p> <p>14 BY MR. ABRAHAM:</p> <p>15 Q But I would like to know what the</p> <p>16 number was. Are you saying you don't know right now</p> <p>17 what that number was?</p> <p>18 A I just said it's the same answer to</p> <p>19 the question, which is -- by definition, it is price</p> <p>20 times quantity that you're seeing here. And that --</p> <p>21 the native price recorded in the IQVIA data for each</p> <p>22 product, month, year and payor is available in the</p> <p>23 IQVIA data. And I'm more than happy to provide it</p> <p>24 to you.</p> <p>25 Q Okay. So same questions for consumer</p>

<p style="text-align: right;">Page 162</p> <p>1 damages, in other words, you would have to look back</p> <p>2 at some data to tell me what the quantity was and</p> <p>3 what the price was that you multiplied to come up</p> <p>4 with your [REDACTED]</p> <p>5 A Right, subject to the criteria of</p> <p>6 inclusion and exclusion, and subject to the</p> <p>7 methodology as outlined in my report, by definition,</p> <p>8 these quantities represent actual quantities and</p> <p>9 prices that were paid by consumers among the</p> <p>10 at-issue drugs in the at-issue time period for the</p> <p>11 at-issue payors.</p> <p>12 Q Right.</p> <p>13 THE COURT REPORTER: I'm sorry, the</p> <p>14 at-issue...</p> <p>15 THE WITNESS: Payors.</p> <p>16 THE COURT REPORTER: Thank you.</p> <p>17 THE WITNESS: The prices for</p> <p>18 consumers.</p> <p>19 BY MR. ABRAHAM:</p> <p>20 Q But, Dr. Conti, I just want to make</p> <p>21 sure, there's no place I can look in your report</p> <p>22 that would tell me what the price and quantity</p> <p>23 numbers are that you used for those two</p> <p>24 calculations; is that fair?</p> <p>25 A Well, what we're providing -- what I'm</p>	<p style="text-align: right;">Page 164</p> <p>1 prospectively.</p> <p>2 Q Does your damages analysis address in</p> <p>3 any way the impact of the recall upon damages to</p> <p>4 either the end-payor or consumer classes?</p> <p>5 A Just in terms of the time period that</p> <p>6 was used.</p> <p>7 Q Okay. Do you know who Hetero's U.S.</p> <p>8 repackager or distributor was in the chain of</p> <p>9 comments?</p> <p>10 A Not off the top of my head, no.</p> <p>11 Q Okay. Do you know what payments, if</p> <p>12 any, were made by that repackager or distributor --</p> <p>13 THE COURT REPORTER: I'm sorry, can</p> <p>14 you repeat that? Can you repeat that?</p> <p>15 MR. ABRAHAM: Sure.</p> <p>16 BY MR. ABRAHAM:</p> <p>17 Q Do you know what payments, if any,</p> <p>18 were made by the repackager or distributor of</p> <p>19 Hetero's product to any party in the chain of</p> <p>20 distribution as a result of the recall?</p> <p>21 A I'm sorry, I don't completely</p> <p>22 understand. What do you mean -- do you mean</p> <p>23 distributor of the wholesale distributor, just to be</p> <p>24 specific?</p> <p>25 Q Let's take -- let's take that example.</p>
<p style="text-align: right;">Page 163</p> <p>1 providing in my report is the conjunction, price</p> <p>2 times quantity. I'm more than happy to provide you</p> <p>3 the -- I think what you're asking for is what is the</p> <p>4 native price and quantity for each -- for Hetero</p> <p>5 underlying the consumer damages listed here. And,</p> <p>6 again, it's in my data. I'm more than happy to</p> <p>7 provide it to you.</p> <p>8 Q Thank you.</p> <p>9 MR. ABRAHAM: I'll make that request,</p> <p>10 please, of your counsel, to provide me with the</p> <p>11 quantity and price that went into your</p> <p>12 end-payor damages and consumer damages</p> <p>13 calculations. I appreciate that.</p> <p>14 BY MR. ABRAHAM:</p> <p>15 Q Do you know the quantity of Hetero's</p> <p>16 valsartan that was recalled as a result of the</p> <p>17 allegedly impure nature of the pills?</p> <p>18 A No. And, again, it was of no moment</p> <p>19 in my analysis because -- because of the significant</p> <p>20 asymmetric information and the perspective of my</p> <p>21 analysis, which was prospectively from the consumer</p> <p>22 and third-party payors' perspective. They had no</p> <p>23 ability to know which products were recalled versus</p> <p>24 which ones were not -- or which ones were</p> <p>25 contaminated versus which ones were not,</p>	<p style="text-align: right;">Page 165</p> <p>1 A Yeah. Okay. So -- and are you asking</p> <p>2 about payments that Hetero made to their distributor</p> <p>3 or --</p> <p>4 Q I mean --</p> <p>5 A -- to other --</p> <p>6 THE COURT REPORTER: Okay. I cannot</p> <p>7 -- I can't have you both speaking at one time.</p> <p>8 It's too fast, and I can't do it.</p> <p>9 MR. ABRAHAM: Sorry. My fault.</p> <p>10 BY THE WITNESS:</p> <p>11 Q I mean, not necessarily payments made</p> <p>12 by Hetero's manufacturer, but made by Hetero's</p> <p>13 United States repackager or distributor.</p> <p>14 A So do you mean that there were --</p> <p>15 there were refunds that were made by the distributor</p> <p>16 to consumers or to third-party payors for recalled</p> <p>17 products?</p> <p>18 Q That's a fair hypothetical. So in</p> <p>19 other words, yes. Did you, in any way in your</p> <p>20 damages analysis, consider if those had occurred and</p> <p>21 what the impact would be in your damages</p> <p>22 calculation?</p> <p>23 A So, again, my -- my damage calculation</p> <p>24 is flexible and could accommodate the possibility of</p> <p>25 refunds that were made for recalled or contaminated</p>

<p style="text-align: right;">Page 166</p> <p>1 product to end-payors. I did not have that data for 2 this analysis that I conducted. My understanding is 3 that whether or not that would be ultimately 4 included in damages for settlement purposes, that is 5 something that would be settled by counsel, court or 6 the judge. 7 Q Okay. Did your damages analysis in 8 any way address the charge backs, rebates, bill 9 backs, administrative fees or cash discounts 10 attributable to sales of Hetero's valsartan that was 11 allegedly contaminated or unpure as a result of the 12 nitrosamine? 13 A That's a really compound question. So 14 let's take that apart. 15 So if discounts were given to 16 consumers at the point of sale, then by definition, 17 they are included in my damages because they would 18 offset the actual payment that patients made at the 19 pharmacy counter. And that would be included in the 20 IQVIA data that's listed in my report. 21 Q Did you analysis -- I'm sorry. Go 22 ahead. I didn't mean to interrupt. 23 A No. It's okay. 24 We don't have rebate data. That is 25 something that is confidential and available from</p>	<p style="text-align: right;">Page 168</p> <p>1 witness. Thank you very much for your time. 2 MR. HONIK: Eric, but for the benefit 3 of the record, I just would like to note that 4 the backup data that you asked of Dr. Conti 5 that pertains to Hetero and Table 1, the 6 aggregate of damages, was provided to you and 7 all defense counsel concomitantly with our 8 serving our class cert motion and brief. So if 9 you'll do nothing more than look at the files 10 that we served, you'll find the data points 11 that you're looking for there. 12 MR. ABRAHAM: Let's have this 13 discussion offline. I don't want to consume 14 the doctor's time. 15 MR. HONIK: Understood. I wanted the 16 record to reflect that it's already been served 17 on counsel. 18 Next -- next up? 19 MR. KNEPPER: Yes. This is 20 Matthew Knepper from Husch Blackwell. I will 21 go next. 22 THE WITNESS: I'm sorry. From where? 23 MR. KNEPPER: Husch Blackwell. I 24 represent Express Scripts. 25 THE WITNESS: -- as the pharmacy, just</p>
<p style="text-align: right;">Page 167</p> <p>1 the manufacturers themselves. From a theory of 2 liability, rebates are not necessarily things that 3 would be considered to be offsets, because injury 4 occurs at the point of sale, and rebates are paid 5 after the products are sold at some other point in 6 time in aggregate and may not be directly related to 7 any specific transaction. 8 But to the extent that Hetero or their 9 agents negotiated prices with third-party payors, 10 that varied by product, they would be in the IQVIA 11 data. Because, by definition, the IQVIA data is 12 providing the price that was actually paid by the 13 third-party at the pharmacy counter for those 14 products. 15 So if discounts were given, if Hetero 16 gave discounts to, I don't know, let's say, take one 17 of the third-party payors in this case, 18 prospectively, that would be in my calculation -- in 19 the damages that are calculated here. 20 THE COURT REPORTER: And what? 21 THE WITNESS: That would be in the 22 damages that are calculated here. 23 MR. ABRAHAM: Okay. Subject to 24 receiving the information that you agreed to 25 provide, I have no further questions for the</p>	<p style="text-align: right;">Page 169</p> <p>1 so I understand. 2 THE COURT REPORTER: I'm sorry? 3 THE WITNESS: I can't hear you. 4 THE COURT REPORTER: What was your 5 last question to Mr. Knepper? 6 THE WITNESS: As the pharmacy benefit 7 manager or as the mail order pharmacy? 8 MR. KNEPPER: As the pharmacy -- the 9 defendant in this case. 10 THE WITNESS: Thank you so much for 11 that clarification. 12 BY MR. KNEPPER: 13 Q So I'd like to turn to Page 32 in your 14 report, Table 3. This is "Aggregate Retailer Unjust 15 Enrichment Damages." Dr. Conti, the dollar figures 16 reflected in Table 3 for unjust enrichment damages 17 represent your calculation of the profits each 18 pharmacy defendant had from the sale of at-issue 19 valsartan, right? 20 A Correct. 21 Q These dollar figures actually reflect 22 the retail pharmacies' profits if the pharmacies 23 obtained the drug for free, right? 24 A No. 25 MR. HONIK: Object to form.</p>

<p style="text-align: right;">Page 170</p> <p>1 BY MR. KNEPPER:</p> <p>2 Q Can you show me where in your</p> <p>3 report -- well, let me strike that.</p> <p>4 Earlier, we talked about dispensing</p> <p>5 fees and how those were removed from -- you said</p> <p>6 removed from the dispensing data produced from the</p> <p>7 retail pharmacies, right?</p> <p>8 THE COURT REPORTER: From the what?</p> <p>9 MR. KNEPPER: From the retail</p> <p>10 pharmacies' data.</p> <p>11 THE WITNESS: Earlier when, sir?</p> <p>12 BY MR. KNEPPER:</p> <p>13 Q Earlier in the deposition when you</p> <p>14 were talking to Ms. Kapke.</p> <p>15 A Sorry, who's Ms. Kathy?</p> <p>16 Q Ms. Kapke, Kara, who questioned you</p> <p>17 this morning.</p> <p>18 A You mean for CVS?</p> <p>19 Q Correct.</p> <p>20 A I am following you now. Thank you for</p> <p>21 the clarification.</p> <p>22 Q Okay. You said that you removed or --</p> <p>23 or took into account the fact that what you called</p> <p>24 dispensing fees were not included in the data that</p> <p>25 was provided by the retail pharmacy defendants in</p>	<p style="text-align: right;">Page 172</p> <p>1 MR. HONIK: Object to the form.</p> <p>2 THE WITNESS: That is of no moment in</p> <p>3 my analysis, sir.</p> <p>4 MR. KNEPPER: Okay. Let's go to</p> <p>5 Paragraph 64, if we could.</p> <p>6 BY MR. KNEPPER:</p> <p>7 Q Okay. Before I ask about</p> <p>8 Paragraph 64, in your experience in this industry,</p> <p>9 would you agree that, before a pharmacy can dispense</p> <p>10 a medication, it has to purchase either a finished</p> <p>11 dose or the active ingredient?</p> <p>12 A Well, most pharmacies, in my</p> <p>13 understanding, have significant stores of</p> <p>14 prescription drugs already available for dispensing.</p> <p>15 Walgreens, for example, and CVS is moving millions</p> <p>16 of prescriptions per day through the U.S. supply</p> <p>17 chain. So those things are not stocked in an</p> <p>18 instantaneous way. They are stocked in a warehouse</p> <p>19 and ready to be dispensed immediately when consumers</p> <p>20 come, especially among generic drugs as frequently</p> <p>21 used as the ones at-issue here.</p> <p>22 Q All right. Is it your understanding</p> <p>23 that the medication that you just referenced, stored</p> <p>24 in Walgreens' warehouse, had to be at one time</p> <p>25 purchased by Walgreens and stored in that warehouse?</p>
<p style="text-align: right;">Page 171</p> <p>1 this case. Do you remember that?</p> <p>2 A That's not what I said, sir. That's a</p> <p>3 mischaracterization of my testimony.</p> <p>4 Q Well, we will go -- I'm not -- I'm not</p> <p>5 trying to be controversial. We can go to page -- or</p> <p>6 Paragraph 78 of the report?</p> <p>7 A No. I mean, why don't we just go to</p> <p>8 the methodology for calculation of unjust enrichment</p> <p>9 in --</p> <p>10 Q Let's go to Page 78 first.</p> <p>11 A -- Paragraph 64 --</p> <p>12 Q Let's go to Paragraph 78.</p> <p>13 THE COURT REPORTER: I can't do this.</p> <p>14 THE WITNESS: In Paragraph 64, where I</p> <p>15 explain that -- that dispensing fees to</p> <p>16 consumers were removed from the calculation,</p> <p>17 the retailer unjust enrichment claims that were</p> <p>18 enumerated by -- offset by pharmacies in</p> <p>19 Table 3.</p> <p>20 BY MR. KNEPPER:</p> <p>21 Q Okay. Other than the statement that</p> <p>22 the -- the dispensing fees were removed, where in</p> <p>23 your report are you taking into account the fact</p> <p>24 that these pharmacies had to pay for the medication</p> <p>25 before they dispensed it.</p>	<p style="text-align: right;">Page 173</p> <p>1 A How is that in any moment to me, sir?</p> <p>2 Q Is that a yes? I need to know. Do</p> <p>3 you agree that Walgreens would have to purchase the</p> <p>4 drug, or do you believe that they get it for free?</p> <p>5 A It's not something, sir, that I</p> <p>6 considered -- it's not in my report. Nowhere do I</p> <p>7 talk about the purchasing of these products by these</p> <p>8 retail pharmacies, because that is not of moment.</p> <p>9 The only thing that is of moment to my</p> <p>10 analysis is that injury occurred at the point of</p> <p>11 sale, and the only cost at the point of sale that is</p> <p>12 relevant is the dispensing fee, which you, the</p> <p>13 retailer, has already taken out of the data. So by</p> <p>14 definition, you have already -- you have already</p> <p>15 said that, yes, that is the cost to you for each</p> <p>16 individual prescription that you moved out of your</p> <p>17 store. You took it out.</p> <p>18 Q Okay. I'm going to move forward.</p> <p>19 This is not my line of questioning.</p> <p>20 Paragraph 63 that you referenced and</p> <p>21 64, Paragraph 63 says, "Retailers profited from the</p> <p>22 sale of the at-issue valsartan," all right? And</p> <p>23 profits are defined as revenue minus costs.</p> <p>24 And so what I'm asking you about is</p> <p>25 how you calculated the profit that is contained in</p>

<p style="text-align: right;">Page 174</p> <p>1 Table 3. And what I understand --</p> <p>2 A I --</p> <p>3 Q I'm not done with my question.</p> <p>4 What I understand is that you took the</p> <p>5 revenue that was reflected as being paid by -- the</p> <p>6 patient responsibility, and you added that up by</p> <p>7 state. And then you note that the dispensing fee is</p> <p>8 not present, but unless you're going to tell me</p> <p>9 there's some other data about the cost to acquire</p> <p>10 the data that you can speak of the drugs that you</p> <p>11 considered, I don't see where you considered the</p> <p>12 cost of purchasing the drug. So can you explain</p> <p>13 where that is in your report?</p> <p>14 MR. HONIK: Object -- hold on a</p> <p>15 second.</p> <p>16 Object to form. Asked and answered.</p> <p>17 You may answer.</p> <p>18 THE WITNESS: Thank you.</p> <p>19 The retail pharmacies subtracted the</p> <p>20 fee, their costs for dispensing the product at</p> <p>21 the point of sale. From their --</p> <p>22 Q I'm not talking about --</p> <p>23 MR. HONIK: You cannot interrupt --</p> <p>24 you cannot interrupt the witness.</p> <p>25 MR. KNEPPER: I'm limited on time.</p>	<p style="text-align: right;">Page 176</p> <p>1 answered.</p> <p>2 THE WITNESS: Sir, I'm going to use</p> <p>3 the -- I'm going to walk you through this as</p> <p>4 best as I possibly can, and simply, so I think</p> <p>5 it will be very clear.</p> <p>6 We asked the pharmacies what their</p> <p>7 profits were, the revenue from the products</p> <p>8 that they sold and their cost. Each retailer</p> <p>9 provided us with only the revenues they</p> <p>10 received from consumer payments, not the amount</p> <p>11 of money that they received from the</p> <p>12 third-party payors, which by definition, would</p> <p>13 be larger than the consumers in this case.</p> <p>14 Instead, the retailers limited the</p> <p>15 data that they produced to just the payments</p> <p>16 that the consumers paid in the form of</p> <p>17 co-insurance and co-payments. The retailers</p> <p>18 also only provided to us information about</p> <p>19 that -- the cost that they viewed as being</p> <p>20 relevant were the dispensing costs.</p> <p>21 BY MR. KNEPPER:</p> <p>22 Q I thought you said that --</p> <p>23 A Excuse me. Hold on, please, sir.</p> <p>24 Please let me finish.</p> <p>25 Q That was a long pause.</p>
<p style="text-align: right;">Page 175</p> <p>1 MR. HONIK: In doesn't matter.</p> <p>2 MR. KNEPPER: She is answering a</p> <p>3 question I am not asking.</p> <p>4 MR. HONIK: You're not permitted to</p> <p>5 cut off the witness. If you -- we can stop the</p> <p>6 deposition. That's up to you, but you can't --</p> <p>7 you can't prevent her from answering.</p> <p>8 MR. KNEPPER: Proceed.</p> <p>9 THE WITNESS: Can you please read back</p> <p>10 the question?</p> <p>11 MR. KNEPPER: I'm going to ask you a</p> <p>12 different one.</p> <p>13 BY MR. KNEPPER:</p> <p>14 Q Can you cite --</p> <p>15 MR. HONIK: Are you withdrawing the</p> <p>16 question?</p> <p>17 MR. KNEPPER: I'm withdrawing the</p> <p>18 question.</p> <p>19 MR. HONIK: Thank you.</p> <p>20 BY MR. KNEPPER:</p> <p>21 Q Can you cite any piece of literature</p> <p>22 to support your idea that one can calculate retail</p> <p>23 pharmacy profits without including, as a cost, the</p> <p>24 pharmacy's cost from actually procuring the goods?</p> <p>25 MR. HONIK: Objection, asked and</p>	<p style="text-align: right;">Page 177</p> <p>1 A Therefore -- therefore, I calculated</p> <p>2 the profits as a function of revenue minus cost,</p> <p>3 where the retailers only provided the payments that</p> <p>4 were made by consumers minus the costs that they</p> <p>5 provided, that they consented to were -- that were</p> <p>6 the dispensing costs. From my perspective, those</p> <p>7 are the costs of dispensing a prescription to an</p> <p>8 individual patient.</p> <p>9 Q So can you point to a treatise that</p> <p>10 supports the idea that you can calculate retail</p> <p>11 pharmacy profits without including a cost of -- that</p> <p>12 the pharmacy spent to procure the goods? Can you</p> <p>13 point to that treatise?</p> <p>14 A This is the retailers' data. It's</p> <p>15 on -- it's on the retailers to provide a treatise to</p> <p>16 support their subtraction of -- or accounting of</p> <p>17 only the dispensing cost. It's not on me. Injury</p> <p>18 occurs at the point of sale. So it's the only thing</p> <p>19 that matters at the point of sale.</p> <p>20 Q To calculate profit?</p> <p>21 A From the retailers' own perspective.</p> <p>22 That is not -- has nothing to do with my</p> <p>23 perspective. That is the retailers' data that was</p> <p>24 provided to me.</p> <p>25 Q All right. The --</p>

<p style="text-align: right;">Page 178</p> <p>1 THE COURT REPORTER: I'm sorry?</p> <p>2 MR. KNEPPER: I was talking to myself.</p> <p>3 Withdraw that. Or strike it.</p> <p>4 BY MR. KNEPPER:</p> <p>5 Q I'm going to take it that, sitting</p> <p>6 here today, you are not going to name a piece of</p> <p>7 literature or treatise that will support the idea</p> <p>8 that you can calculate the -- the profits of a</p> <p>9 pharmacy if you don't include the amount of money</p> <p>10 that the pharmacy spent procuring the goods?</p> <p>11 MR. HONIK: Object to form. It's been</p> <p>12 asked and answered. It's painfully clear that</p> <p>13 you don't understand, and I -- I -- she can't</p> <p>14 answer it any differently.</p> <p>15 MR. KNEPPER: Okay. Then we'll move</p> <p>16 on. I withdraw the question. I withdraw the</p> <p>17 question.</p> <p>18 THE WITNESS: I don't --</p> <p>19 MR. KNEPPER: I'm withdrawing the</p> <p>20 question.</p> <p>21 THE COURT REPORTER: I can't hear</p> <p>22 anybody. I hear nobody.</p> <p>23 THE WITNESS: I don't -- are you</p> <p>24 withdrawing the question and striking the</p> <p>25 question? Because I'm more than happy to</p>	<p style="text-align: right;">Page 180</p> <p>1 dispensing. I believe earlier you testified --</p> <p>2 A No, that's not --</p> <p>3 Q I'm not done asking my question.</p> <p>4 Earlier, you testified that a pharmacy</p> <p>5 sets the dispensing fee. And I want to clarify my</p> <p>6 understanding as -- in this industry is that</p> <p>7 typically, the dispensing fee is set by a PBM as</p> <p>8 part of the network agreement. Is that true?</p> <p>9 A That is not my understanding because</p> <p>10 there are many, many dispensing prescription drugs</p> <p>11 that have nothing to do with a pharmacy benefit</p> <p>12 manager.</p> <p>13 Q I don't understand that answer.</p> <p>14 MR. HONIK: Are you just going to make</p> <p>15 comments and speak to yourself and create a</p> <p>16 record?</p> <p>17 MR. KNEPPER: Is that an objection?</p> <p>18 THE WITNESS: That's what you're</p> <p>19 doing.</p> <p>20 MR. HONIK: That's what you're doing.</p> <p>21 You're just -- it's like a color commentary to</p> <p>22 the testimony. You're here and permitted to</p> <p>23 ask a question and receive an answer. That's</p> <p>24 it. You're not supposed to -- you know, reveal</p> <p>25 your own befuddlement at the answers.</p>
<p style="text-align: right;">Page 179</p> <p>1 answer your question.</p> <p>2 BY MR. KNEPPER:</p> <p>3 Q No, I'm going to withdraw.</p> <p>4 I feel like if there was a treatise</p> <p>5 available, or treatise or an article or piece of</p> <p>6 literature to support it, you would have named it.</p> <p>7 I'm going to move forward.</p> <p>8 MR. HONIK: Move to strike. That's</p> <p>9 not a -- excuse me. That's not a question.</p> <p>10 You can't testify.</p> <p>11 MR. KNEPPER: Got it.</p> <p>12 BY MR. KNEPPER:</p> <p>13 Q You understand that a dispensing fee</p> <p>14 is typically set by a pharmacy benefit manager as</p> <p>15 part of a pharmacy being in that pharmacy benefit</p> <p>16 manager's network, right?</p> <p>17 MR. HONIK: Objection, asked and</p> <p>18 answered.</p> <p>19 THE WITNESS: That is not my</p> <p>20 answer -- that is not my understanding, sir.</p> <p>21 There are many, many transactions here that</p> <p>22 have nothing to do with the existence of a</p> <p>23 pharmacy benefit manager.</p> <p>24 BY MR. KNEPPER:</p> <p>25 Q I asked about the setting of a</p>	<p style="text-align: right;">Page 181</p> <p>1 BY MR. KNEPPER:</p> <p>2 Q Under the -- you went -- in order to</p> <p>3 calculate your damages model, I believe earlier you</p> <p>4 said you tallied up the total amount of patient</p> <p>5 responsibilities by state. And then you put on the</p> <p>6 charts other and attached it to your report, right?</p> <p>7 That's how you got to the full amount of damages?</p> <p>8 A I don't understand your question.</p> <p>9 MR. HONIK: Object to form.</p> <p>10 BY MR. KNEPPER:</p> <p>11 Q Are you aware that in some</p> <p>12 circumstances a pharmacy might end up actually being</p> <p>13 reimbursed less than the amount it paid to acquire a</p> <p>14 drug?</p> <p>15 MR. HONIK: Object to form, asked and</p> <p>16 answered.</p> <p>17 You can respond.</p> <p>18 THE WITNESS: I don't understand the</p> <p>19 question, sir.</p> <p>20 BY MR. KNEPPER:</p> <p>21 Q Are you aware as an -- as someone who</p> <p>22 is familiar with the industry and these</p> <p>23 circumstances, which -- because of the reimbursement</p> <p>24 that is offered by a third-party payor otherwise,</p> <p>25 that a pharmacy may end up receiving less than the</p>

<p style="text-align: right;">Page 182</p> <p>1 amount indicated in the expense to acquire the drug?</p> <p>2 MR. HONIK: Object to the form, asked</p> <p>3 and answered. Are you referring to pre- and</p> <p>4 post-point of sale transactions?</p> <p>5 MR. KNEPPER: I mean, I'm asking the</p> <p>6 question.</p> <p>7 MR. HONIK: She answered you. She</p> <p>8 said she doesn't --</p> <p>9 MR. KNEPPER: No, you answered it.</p> <p>10 MR. HONIK: No, I didn't answer it.</p> <p>11 MR. KNEPPER: You answered another</p> <p>12 question.</p> <p>13 MR. HONIK: She didn't understand your</p> <p>14 question. I'm trying -- I'm trying to help</p> <p>15 you.</p> <p>16 MR. KNEPPER: I'm going to stop.</p> <p>17 MR. HONIK: Okay.</p> <p>18 MR. OSTFELD: I think that means I'm</p> <p>19 up.</p> <p>20 EXAMINATION BY MR. OSTFELD:</p> <p>21 Q Good afternoon, Doctor.</p> <p>22 THE COURT REPORTER: Hold on. Who's</p> <p>23 going next?</p> <p>24 MR. OSTFELD: This is Greg Ostfeld --</p> <p>25 THE COURT REPORTER: Hold on.</p>	<p style="text-align: right;">Page 184</p> <p>1 manufacturers like Teva, did you make any</p> <p>2 adjustments to account for differences in different</p> <p>3 states, measures and damages?</p> <p>4 MR. HONIK: Note my objection, asked</p> <p>5 and answered. And to the extent it calls for a</p> <p>6 legal conclusion, I further object.</p> <p>7 But you may answer.</p> <p>8 THE WITNESS: We have already talked</p> <p>9 about this numerous times. So the theories of</p> <p>10 liability and unjust enrichment are by</p> <p>11 definition state specific. And therefore, the</p> <p>12 calculations are, for each of the damage</p> <p>13 calculations that are presented in my report,</p> <p>14 are month, year, product and state specific.</p> <p>15 BY MR. OSTFELD:</p> <p>16 Q Okay. And those calculations are</p> <p>17 agnostic with respect to the state law measure of</p> <p>18 damage for each state, correct?</p> <p>19 MR. HONIK: Object to the form, asked</p> <p>20 and answered.</p> <p>21 THE WITNESS: Again, my understanding</p> <p>22 is that they are based on instruction from</p> <p>23 counsel.</p> <p>24 BY MR. OSTFELD:</p> <p>25 Q Okay. So when you get instructions</p>
<p style="text-align: right;">Page 183</p> <p>1 MR. OSTFELD: -- from Greenberg</p> <p>2 Traurig.</p> <p>3 THE WITNESS: I'm sorry, I'd like to</p> <p>4 take a break. I'll take five minutes, please.</p> <p>5 MR. HONIK: Okay.</p> <p>6 THE VIDEOGRAPHER: The time is 4:34.</p> <p>7 We're going off the record.</p> <p>8 (Whereupon, a short break was taken.)</p> <p>9 THE VIDEOGRAPHER: The time is 4:40.</p> <p>10 We're back on the record.</p> <p>11 BY MR. OSTFELD:</p> <p>12 Q Good afternoon, Dr. Conti. My name's</p> <p>13 Greg Ostfeld. And I represent the Teva group of</p> <p>14 defendants, which includes both Teva and Actavis.</p> <p>15 The good news is you're almost done.</p> <p>16 So --</p> <p>17 A I hope you don't yell at me like the</p> <p>18 previous attorney, or bully me.</p> <p>19 Q I'm not a yeller, Dr. Conti.</p> <p>20 A That sounds good.</p> <p>21 Q I mean, if we can try to be nice to</p> <p>22 each other for the last 15 minutes, we can end on an</p> <p>23 upbeat note going into the weekend.</p> <p>24 A Okay.</p> <p>25 Q When you calculated damages for</p>	<p style="text-align: right;">Page 185</p> <p>1 from counsel, the court or a jury, that would be</p> <p>2 when you would make adjustments to account for</p> <p>3 state-specific differences?</p> <p>4 MR. HONIK: Object to form.</p> <p>5 THE WITNESS: I think I'm a little</p> <p>6 confused.</p> <p>7 What I'm saying is, my damage</p> <p>8 calculations that are presented in this report</p> <p>9 are already adjusted for state-specific issues.</p> <p>10 And there might be additional adjustments that</p> <p>11 are made. My method is flexible to account for</p> <p>12 them and would be up to the court or the jury</p> <p>13 to decide.</p> <p>14 BY MR. OSTFELD:</p> <p>15 Q All right. In my client's case, you</p> <p>16 calculated separate damages for their generic</p> <p>17 versions of Diovan and Exforge; is that right?</p> <p>18 THE COURT REPORTER: Diovan and -- I'm</p> <p>19 sorry.</p> <p>20 MR. OSTFELD: Exforge.</p> <p>21 THE COURT REPORTER: Yes. Uh-huh.</p> <p>22 THE WITNESS: That is my</p> <p>23 understanding, yes.</p> <p>24 BY MR. OSTFELD:</p> <p>25 Q Okay. Now, the brand-name versions of</p>

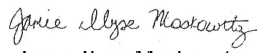
<p style="text-align: right;">Page 186</p> <p>1 those two drugs, those were not adulterated or</p> <p>2 misbranded under the assumptions you've applied to</p> <p>3 your method, correct?</p> <p>4 MR. HONIK: Object to the form.</p> <p>5 THE WITNESS: I don't understand. I'm</p> <p>6 sorry.</p> <p>7 BY MR. OSTFELD:</p> <p>8 Q That's okay. You were not asked to</p> <p>9 assume that brand-name Diovan was adulterated or</p> <p>10 misbranded for purposes of your analysis of this</p> <p>11 case, correct?</p> <p>12 A So the products that are at issue are</p> <p>13 enumerated in Footnote 3 and discussed in -- at</p> <p>14 length in the complaint. The attorneys, the</p> <p>15 counsel, gave me the NDC codes and the month, years</p> <p>16 at issue. And that's what was applied to the data</p> <p>17 that I got from IQVIA or to the retailers as we've</p> <p>18 already discussed at length.</p> <p>19 Q Okay. And you have not applied the</p> <p>20 assumptions of adulteration or misbranding to any</p> <p>21 other forms of valsartan beyond those that</p> <p>22 were -- that you just described that are delineated</p> <p>23 in your footnote and that were provided to you by</p> <p>24 counsel by NDC code?</p> <p>25 MR. HONIK: Object to form.</p>	<p style="text-align: right;">Page 188</p> <p>1 different assumption from the assumption that you</p> <p>2 made in preparing your analysis in this case.</p> <p>3 Plaintiffs' counsel asked you to make one</p> <p>4 assumption, I'm going to now ask you to make a</p> <p>5 different one.</p> <p>6 I will ask you to assume, for the</p> <p>7 purposes of my next few questions -- and I know you</p> <p>8 don't love hypotheticals. But we're talking about</p> <p>9 assumptions here, so I'm going to have to ask you to</p> <p>10 make a few.</p> <p>11 So I will ask you to assume, for</p> <p>12 purposes of my next questions, that some</p> <p>13 manufacturers' versions of generic valsartan were</p> <p>14 not adulterated and/or not misbranded. Okay?</p> <p>15 That's the assumption I'm asking you to make. The</p> <p>16 question is coming.</p> <p>17 A In what time period, sir?</p> <p>18 Q During the same time period that the</p> <p>19 at-issue valsartan was being sold.</p> <p>20 A Okay. And they were in the retail</p> <p>21 profit trade in the U.S.?</p> <p>22 Q Yes.</p> <p>23 A And their non-contamination was known</p> <p>24 by the manufacturer and also communicated to the</p> <p>25 FDA?</p>
<p style="text-align: right;">Page 187</p> <p>1 THE WITNESS: Again, counsel provided</p> <p>2 me the list of NDC codes. We picked up a</p> <p>3 number of additional NDC codes that were</p> <p>4 repackaged or private-labeled but were related</p> <p>5 to the upstream at-issue products, and then</p> <p>6 applied that forward to the calculation.</p> <p>7 BY MR. OSTFELD:</p> <p>8 Q All right. During the same time</p> <p>9 period that the at-issue valsartan was sold, did</p> <p>10 brand-name Diovan have a legitimate supply curve?</p> <p>11 A Again, my opinion related to the</p> <p>12 legitimate supply curve is related to the products</p> <p>13 at-issue.</p> <p>14 Q Right. And that's all I'm asking you.</p> <p>15 For one of the products that's not at issue,</p> <p>16 brand-name Diovan, did it have a legitimate supply</p> <p>17 curve?</p> <p>18 MR. HONIK: Object to the form. It's</p> <p>19 been asked and answered, and it's beyond the</p> <p>20 scope.</p> <p>21 You may respond.</p> <p>22 THE WITNESS: Yeah. I don't quite</p> <p>23 understand your question. I'm sorry.</p> <p>24 BY MR. OSTFELD:</p> <p>25 Q Okay. I'm going to ask you to make a</p>	<p style="text-align: right;">Page 189</p> <p>1 Q That -- sure. We can make that</p> <p>2 assumption as well.</p> <p>3 A And it was also asserted to or</p> <p>4 attested to by those manufacturers to the</p> <p>5 Food and Drug Administration and the downstream</p> <p>6 consumers?</p> <p>7 Q That they were not adulterated and not</p> <p>8 misbranded, yes. You can make that assumption as</p> <p>9 well.</p> <p>10 A Great. And those attestations were</p> <p>11 not incorrect, in fact?</p> <p>12 Q That is -- that is the assumption I'm</p> <p>13 asking to you make, yes.</p> <p>14 A Okay. Just trying to understand</p> <p>15 exactly what contours of the hypothetical are.</p> <p>16 Q Absolutely. I like that you are</p> <p>17 precise, and I want to make sure you have a good set</p> <p>18 of assumptions. So you're comfortable with those</p> <p>19 assumptions?</p> <p>20 MR. HONIK: Object to the form.</p> <p>21 THE WITNESS: I'll let you know if I</p> <p>22 have other questions.</p> <p>23 BY MR. OSTFELD:</p> <p>24 Q Okay. Using the assumptions that</p> <p>25 we've just agreed to, would it be your opinion that</p>

<p style="text-align: right;">Page 190</p> <p>1 there was a legitimate supply curve for</p> <p>2 non-adulterated, non-misbranded, generic valsartan</p> <p>3 drugs, applying all of the assumptions you just</p> <p>4 made?</p> <p>5 A Yes, from a -- from a prospective form</p> <p>6 perspective, if the products were not adulterated,</p> <p>7 not misbranded and -- and were cGMP compliant in</p> <p>8 their material production, and met all of the rest</p> <p>9 of the FDA requirements, safety, efficacy, purity,</p> <p>10 et cetera, then yes, correct. They would be a --</p> <p>11 there is a legitimate supply curve for those</p> <p>12 products.</p> <p>13 Q And would that apply retrospectively,</p> <p>14 as well, to the products that were already sold and</p> <p>15 ingested?</p> <p>16 A No.</p> <p>17 Q And why not?</p> <p>18 A Because my analysis is a prospective</p> <p>19 one, not a retrospective one.</p> <p>20 Q Understood.</p> <p>21 So your analysis could not apply</p> <p>22 retrospectively. Understood.</p> <p>23 A No. That's not what I said, sir.</p> <p>24 That's not my testimony.</p> <p>25 Q Okay. That's okay. I'll move on.</p>	<p style="text-align: right;">Page 192</p> <p>1 payors?</p> <p>2 A I just asked you about the condition</p> <p>3 of asymmetric information. If -- if consumers and</p> <p>4 third-party payors, plus the regulator, all knew the</p> <p>5 exact same information that the manufacturer did</p> <p>6 regarding the purity, strength, adulteration or</p> <p>7 non-adulteration, non-misbranding, et cetera, if the</p> <p>8 product was exactly what it said it was or what was</p> <p>9 represented, and every consumer and third-party</p> <p>10 payor had full transparency over that, then, yes,</p> <p>11 prospectively, that would make absolute sense that</p> <p>12 there was full economic value.</p> <p>13 Q Okay.</p> <p>14 A We, of course, don't live in a world</p> <p>15 of full information.</p> <p>16 Q Okay. I understand that you have</p> <p>17 relied on the allegations of the complaint</p> <p>18 referenced in Footnote 1 in the first paragraph of</p> <p>19 your report as the basis for your assumption of</p> <p>20 adulteration and misbranding; is that correct?</p> <p>21 A I'm sorry. There's a -- there's</p> <p>22 numerous things that you said in that sentence,</p> <p>23 so --</p> <p>24 Q Okay. I guess what I'm trying to --</p> <p>25 I'm not asking to you repeat testimony, but I want</p>
<p style="text-align: right;">Page 191</p> <p>1 Under the same changed assumptions</p> <p>2 that we just agreed to, would you agree that</p> <p>3 non-adulterated, non-misbranded, generic valsartan</p> <p>4 drugs have economic value as well as therapeutic</p> <p>5 value?</p> <p>6 MR. HONIK: Object to the form.</p> <p>7 THE WITNESS: I have no opinion on</p> <p>8 therapeutic value. It was not of any moment in</p> <p>9 my analysis because therapeutic value is -- is</p> <p>10 related to the demand curve. And I'm not</p> <p>11 analyzing the demand curve here. I'm focused</p> <p>12 on the supply curve.</p> <p>13 BY MR. OSTFELD:</p> <p>14 Q Okay. I'll exclude therapeutic value</p> <p>15 from my question.</p> <p>16 Under the same assumptions that we</p> <p>17 just agreed to, would you agree that</p> <p>18 non-adulterated, non-misbranded generic valsartan</p> <p>19 drugs have economic value?</p> <p>20 A In -- where there was no asymmetric</p> <p>21 information?</p> <p>22 Q Correct.</p> <p>23 A Yes.</p> <p>24 Q And that economic value was true --</p> <p>25 would be true of both consumers and third-party</p>	<p style="text-align: right;">Page 193</p> <p>1 to make sure I accurately understand your earlier</p> <p>2 testimony.</p> <p>3 I think I understood you earlier to</p> <p>4 testify that the basis for your assumption that the</p> <p>5 at-issue valsartan was adulterated and misbranded,</p> <p>6 is what is contained in the complaint in this case;</p> <p>7 is that correct?</p> <p>8 MR. HONIK: Object to form,</p> <p>9 mischaracterizes the testimony. You can</p> <p>10 respond.</p> <p>11 THE WITNESS: As instructed by counsel</p> <p>12 and laid out in my report, yes.</p> <p>13 THE COURT REPORTER: I'm sorry. I've</p> <p>14 been instructed by counsel...</p> <p>15 MR. HONIK: As instructed.</p> <p>16 THE WITNESS: As instructed by counsel</p> <p>17 and laid out in my report.</p> <p>18 THE COURT REPORTER: Thank you.</p> <p>19 BY MR. OSTFELD:</p> <p>20 Q Other than the complaint, is there any</p> <p>21 other basis on which you have relied for your</p> <p>22 assumption that the at-issue valsartan of my</p> <p>23 clients, Teva, was adulterated and misbranded?</p> <p>24 MR. HONIK: Object to form, asked and</p> <p>25 answered.</p>

<p style="text-align: right;">Page 194</p> <p>1 THE WITNESS: Well, I think we've</p> <p>2 already talked about this, that the FDA had</p> <p>3 very -- there was a lot of communications about</p> <p>4 the products at-issue and the contamination,</p> <p>5 which includes discussions of the contamination</p> <p>6 and the recall for the Teva-specific products.</p> <p>7 BY MR. OSTFELD:</p> <p>8 Q Do you have any personal knowledge of</p> <p>9 whether Teva's valsartan was adulterated or</p> <p>10 misbranded?</p> <p>11 A Define "personal knowledge," sir.</p> <p>12 Q Is it your opinion that Teva violated</p> <p>13 good -- current good manufacturing practices?</p> <p>14 MR. HONIK: Object to form.</p> <p>15 THE WITNESS: I mean, we talked about</p> <p>16 this earlier. I'd be more than happy to go</p> <p>17 through what the FDA said. It's --</p> <p>18 THE COURT REPORTER: I'm sorry. What</p> <p>19 was just said?</p> <p>20 MR. OSTFELD: Guys, somebody needs to</p> <p>21 mute.</p> <p>22 MR. HONIK: It's Eric Abraham.</p> <p>23 THE COURT REPORTER: Okay. So we</p> <p>24 talked about this earlier. I'm more than happy</p> <p>25 to go through what the FDA said...</p>	<p style="text-align: right;">Page 196</p> <p>1 this case an original document that you prepared</p> <p>2 specifically for this case?</p> <p>3 MR. HONIK: Object to form. What do</p> <p>4 you mean by "original"?</p> <p>5 THE WITNESS: Yeah. I don't</p> <p>6 understand what that means.</p> <p>7 BY MR. OSTFELD:</p> <p>8 Q Are there any parts of your</p> <p>9 declaration in this case that you copied or adapted</p> <p>10 from another report in your case?</p> <p>11 A What other case?</p> <p>12 Q I'm asking you. Are there any parts</p> <p>13 of your declaration in this case that you copied or</p> <p>14 adapted from an earlier report in another case?</p> <p>15 A I'm asking you to be specific, sir.</p> <p>16 Q Any case, any report in any other</p> <p>17 case.</p> <p>18 A I mean, I'm happy to go through and</p> <p>19 look. Certainly, there are parts of my</p> <p>20 qualifications that are pretty standard. So if we</p> <p>21 can go through -- so we go -- I'm answering your</p> <p>22 question, sir.</p> <p>23 Q I'm not asking you to go through your</p> <p>24 report. I'm asking --</p> <p>25 A I have asked you for specifics several</p>
<p style="text-align: right;">Page 195</p> <p>1 BY MR. OSTFELD:</p> <p>2 Q Doctor, I'll withdraw my question. I</p> <p>3 see that I'm running short on time, and there's one</p> <p>4 more topic I wanted to cover.</p> <p>5 MR. HONIK: I think there's only a</p> <p>6 minute or so left.</p> <p>7 MR. OSTFELD: I think 2:45 is what</p> <p>8 I've got on my timer.</p> <p>9 BY MR. OSTFELD:</p> <p>10 Q You told Mr. Goldberg yesterday that</p> <p>11 you wrote your declaration in this case. Did you</p> <p>12 write the entire declaration?</p> <p>13 A I'm sorry, is that a compound</p> <p>14 question?</p> <p>15 Q No. I'm asking, did you write your</p> <p>16 entire declaration in this case? It's one question.</p> <p>17 A Are you asking me about what I said to</p> <p>18 Mr. Goldberg?</p> <p>19 Q I'm asking you a separate question.</p> <p>20 Did you write your entire declaration in this case?</p> <p>21 A I wrote my declaration in this case.</p> <p>22 Q Did anyone else draft any --</p> <p>23 A Hold on. With the assistance of my</p> <p>24 staff.</p> <p>25 Q All right. Is your declaration in</p>	<p style="text-align: right;">Page 197</p> <p>1 times. You --</p> <p>2 Q All right. Well, I'm going to</p> <p>3 withdraw my question.</p> <p>4 A -- and now I'm going to try to answer</p> <p>5 it.</p> <p>6 Q I'm going to withdraw my question, and</p> <p>7 ask you a more specific question.</p> <p>8 You previously prepared an expert</p> <p>9 report in Blue Cross Blue Shield Association versus</p> <p>10 GlaxoSmithKline?</p> <p>11 A I'm sorry, what case is that, sir?</p> <p>12 Q Blue Cross Blue Shield Association</p> <p>13 versus GlaxoSmithKline.</p> <p>14 A Can you refer to me in my CV which</p> <p>15 case that is?</p> <p>16 Q Did you copy or adapt portions of your</p> <p>17 expert report in this case from your report in</p> <p>18 Blue Cross Blue Shield Association versus</p> <p>19 GlaxoSmithKline?</p> <p>20 A I'm asking you which specific case is</p> <p>21 that. Can you point to me in my CV or in my</p> <p>22 declaration what case that is?</p> <p>23 MR. HONIK: Excuse me. Or</p> <p>24 alternatively, show the witness the other</p> <p>25 document, and she will compare it and answer</p>

<p style="text-align: right;">Page 198</p> <p>1 your question, either way.</p> <p>2 BY MR. OSTFELD:</p> <p>3 Q That is the name of the case in your</p> <p>4 CV, ma'am.</p> <p>5 A Okay. So show me where it is in my</p> <p>6 CV.</p> <p>7 Q I don't have your CV in front of me,</p> <p>8 but let me pull it up.</p> <p>9 A Okay.</p> <p>10 Q If you look on Page 5 of your CV, the</p> <p>11 second to last --</p> <p>12 A Give me a second to get there.</p> <p>13 Page 5. Okay. So there are multiple reports, June,</p> <p>14 August, September 2018. Blue Cross Blue Shield</p> <p>15 Association et al. versus GlaxoSmithKline. Is that</p> <p>16 the one you're talking about?</p> <p>17 Q That is the case that I'm talking</p> <p>18 about.</p> <p>19 A And it says, "Written reports," with</p> <p>20 an S, "and deposition," correct?</p> <p>21 Q Correct.</p> <p>22 A Okay. So as I mentioned before,</p> <p>23 before you interrupted me, my qualifications don't</p> <p>24 change much. So I'm assuming if we go to Page 4 of 24</p> <p>25 this report, of the current report, I expect that</p>	<p style="text-align: right;">Page 200</p> <p>1 also provided in my CV.</p> <p>2 17 probably hasn't changed so much.</p> <p>3 18 definitely has changed. 19 may or may not</p> <p>4 be in that report. Then we can go through the</p> <p>5 institutional background on the regulation.</p> <p>6 BY MR. OSTFELD:</p> <p>7 Q Okay.</p> <p>8 A So that other case was also a cGMP</p> <p>9 case, and many of the institutions are obviously the</p> <p>10 same. Probably, there is overlap.</p> <p>11 Q To complete this exercise, would it be</p> <p>12 helpful to you if I put the other report in so you</p> <p>13 can compare them side-by-side?</p> <p>14 A I mean, there are actually multiple</p> <p>15 reports, and there's a deposition. So which -- I'd</p> <p>16 like to see them all.</p> <p>17 Q Well, I only have one, but I'll put it</p> <p>18 on the screen. And if you --</p> <p>19 A I'm sorry. If you're going to provide</p> <p>20 new information to me and ask me to compare and</p> <p>21 contrast and go through, then I'd like to see them</p> <p>22 all.</p> <p>23 Q Dr. Conti, I only have one. I can</p> <p>24 only give you what I have.</p> <p>25 A Then I think -- then I think that we</p>
<p style="text-align: right;">Page 199</p> <p>1 Paragraph 12 and probably Paragraph 13, probably</p> <p>2 Paragraph 14, in whole or in part -- I think that</p> <p>3 changed a little over time. Certainly Paragraph 15</p> <p>4 has changed over time, because I've added that I've</p> <p>5 been a consultant for the FDA's office of generic</p> <p>6 drugs, that I'm currently serving as an ad hoc</p> <p>7 advisor to the national finance -- advisor to the</p> <p>8 Engineering invention -- Medicine's Committee on the</p> <p>9 security --</p> <p>10 THE COURT REPORTER: I'm sorry, one</p> <p>11 more -- you're serving as an ad hoc advisor to</p> <p>12 the...</p> <p>13 THE WITNESS: I am currently serving</p> <p>14 as an ad hoc advisor to the National Academy of</p> <p>15 Sciences, Engineering and Medicine's Committee</p> <p>16 on Security of America's Medical Supply --</p> <p>17 Product Supply Change. That's new.</p> <p>18 So 16 has definitely been updated to</p> <p>19 reflect the fact that I was -- that I have</p> <p>20 submitted testimony in another cGMP violation</p> <p>21 matter, which is the case that we were just</p> <p>22 talking about, the Blue Cross Blue Shield</p> <p>23 versus GlaxoSmithKline case. But also, that</p> <p>24 I've been involved in a variety of other cases</p> <p>25 since that case concluded. That information is</p>	<p style="text-align: right;">Page 201</p> <p>1 don't have enough time to do this, in all fairness.</p> <p>2 I'm more than happy to go through, line-by-line, my</p> <p>3 report and other reports. But, you know, if you're</p> <p>4 going to refer me to the reports that I -- that I</p> <p>5 wrote for the center case, I want to do them all,</p> <p>6 not just one, and not just cherry pick things that</p> <p>7 might be convenient for you, but everything.</p> <p>8 MR. HONIK: Yeah. And I think our</p> <p>9 time is up. Justin, can you report to us where</p> <p>10 we are?</p> <p>11 THE VIDEOGRAPHER: Do you want me to</p> <p>12 go off the record and do that?</p> <p>13 MR. HONIK: Sure, off the record.</p> <p>14 THE VIDEOGRAPHER: We are going off</p> <p>15 the record. The time is 5:00 p.m.</p> <p>16 (Whereupon, a discussion was held off</p> <p>17 the record.)</p> <p>18 MR. HONIK: Counsel has exceeded the</p> <p>19 10-hour limit, number 1. Number 2, with --</p> <p>20 astonishingly, with about 60 or 30 seconds</p> <p>21 left, he produced one of, apparently, multiple</p> <p>22 reports that are revealed in Dr. Conti's CV,</p> <p>23 and has asked her to determine what parts of</p> <p>24 it, if any, are replicated or appear in the</p> <p>25 current report. She's not had an opportunity</p>

Page 202	Page 204
<p>1 to look at the document, and now defendants 2 exist -- insist, having exceeded the 10-hour 3 limit, to mark an exhibit that the witness has 4 not seen or been given an opportunity to 5 review. Therefore, I object to its being 6 marked. 7 It's sort of like piling on at the end 8 and clipping news articles and asking them to 9 be attached as exhibits. It's entirely 10 improper. You haven't asked the witness a 11 single question, nor has she had an opportunity 12 to look at it, and I object. 13 MR. OSTFELD: I will state, for the 14 record, that the question I asked the witness 15 was, "Did you copy or adapt portions of your 16 expert report from Blue Cross Blue Shield 17 Association versus GlaxoSmithKline for your 18 declaration in this case?" 19 The witness then indicated that she 20 wished to go, paragraph by paragraph, through 21 her report and to compare it to the reports 22 from Blue Cross Blue Shield Association. 23 MR. HONIK: She did no such thing. 24 THE WITNESS: -- mischaracterizing my 25 statement --</p>	<p>1 of the document. She merely asked to look at 2 the document. And for minutes that took you 3 past, as a matter of fact, the 10-hour limit, 4 it's not my position that you went past the 5 10-hour time limit. You went past the 10-hour 6 time limit. 7 And you then finally offered her one 8 of the multiple reports that she prepared. And 9 she tried to answer your question, and it 10 ended. That's an improper use of an exhibit. 11 It is beyond the pale to have done so with 30 12 or 60 seconds. It's the worst form of lawyerly 13 got you imaginable, and I object. And we'll 14 move to strike at the appropriate time. 15 I can't prevent you saying it's 16 being -- it's being marked, but we will move to 17 strike it. And it is really unseemly that you 18 have chosen to do that. 19 That concludes the deposition. 20 MR. OSTFELD: This report is being 21 marked, and I will provide -- 22 THE COURT REPORTER: I can only do 23 this one at a time. Greg -- Greg, this report 24 is being marked... 25 MR. OSTFELD: Hang on. Madam Court</p>
Page 203	Page 205
<p>1 MR. OSTFELD: Excuse me. Excuse me. 2 Please -- please allow me to finish my 3 statement for record, Ruben. I didn't 4 interrupt you. 5 And, Dr. Conti, I didn't interrupt 6 you. And these are being -- these are -- these 7 are records that are being made for the court. 8 So I then put into the record the one 9 report that I have in my possession from that 10 case so that Dr. Conti could reference it to 11 complete her analysis. There was a question 12 pending. We were trying to answer it in the 13 manner in which she wanted to answer it, which 14 was going through her report. And Mr. Honik 15 has now taken the view that time has expired. 16 I would object to terminating the 17 deposition when there was a pending question 18 and where counsel was attempting to provide 19 Dr. Conti with the mechanism she asked for to 20 answer the question. 21 MR. HONIK: Yeah. Mr. Ostfeld, that 22 is about as big a distortion as one could -- 23 could possibly state. The witness did not ask 24 to go line by line. You asked her a question 25 without the -- excuse me -- without the benefit</p>	<p>1 Reporter, can you please hang on? I'll let 2 you -- don't talk over me so that you can't 3 hear what I'm saying. 4 Ruben, we know you are concluding the 5 deposition, but you can't do it the way you are 6 doing it. Okay? We still have to finish the 7 deposition the right way. You can't just stop 8 it. Okay. Yes, we can't just go off the 9 record in a ladder. 10 MR. HONIK: Yes, we're -- 11 MR. GOLDBERG: Now, I'm gonna say 12 something, Ruben. 13 Dr. Conti, during the deposition, you 14 were texted by counsel. I'm going to ask you 15 that you not delete that text. Do not delete 16 any text that you received from counsel during 17 this deposition. 18 MR. HONIK: You're mischaracterizing 19 the record. 20 MR. GOLDBERG: Ruben -- 21 MR. HONIK: No. No. No. No. 22 MR. GOLDBERG: We will address this 23 issue later, but it is important that this 24 record be preserved. And I don't want 25 Dr. Conti to leave until we have made that</p>

<p style="text-align: right;">Page 206</p> <p>1 record.</p> <p>2 MR. HONIK: You can make whatever</p> <p>3 record you want.</p> <p>4 MR. GOLDBERG: Now --</p> <p>5 THE COURT REPORTER: I can't do this.</p> <p>6 I can't. I can't do it. One at a time. One</p> <p>7 at a time.</p> <p>8 MR. GOLDBERG: Okay. Now that we have</p> <p>9 done that -- okay. Let the record reflect that</p> <p>10 the witness has just walked away during the</p> <p>11 deposition.</p> <p>12 MR. HONIK: Are you 12 years old,</p> <p>13 Seth?</p> <p>14 MR. GOLDBERG: No.</p> <p>15 MR. HONIK: As far as the witness is</p> <p>16 concerned, it's over. There are no more</p> <p>17 questions that you may be permitted to ask</p> <p>18 Dr. Conti. She can get up and stretch her</p> <p>19 legs, do whatever she wishes in the world,</p> <p>20 number 1.</p> <p>21 Number 2, Mr. Ostfeld apparently has</p> <p>22 now attached as an exhibit a report that makes</p> <p>23 reference to an Austin and Burke PowerPoint</p> <p>24 that Teva clawed back. So Teva has now waived</p> <p>25 their privilege as to that document being</p>	<p style="text-align: right;">Page 208</p> <p>1 am attaching as an exhibit and putting in.</p> <p>2 And I will provide it to the court</p> <p>3 reporter as an exhibit. And we certainly do</p> <p>4 not waive anything that is not in the public</p> <p>5 court file in that case.</p> <p>6 (Whereupon, Exhibit Conti 8 was marked</p> <p>7 for Identification.)</p> <p>8 MR. HONIK: Anything else?</p> <p>9 MR. OSTFELD: That's it for me.</p> <p>10 MR. HONIK: We're concluded. Thank</p> <p>11 you, Jamie.</p> <p>12 (Whereupon, the deposition concluded</p> <p>13 at 5:08 p.m.)</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 207</p> <p>1 admitted into evidence into this case. Is</p> <p>2 there anything else you need to say?</p> <p>3 MR. GOLDBERG: Yeah, I do. And then</p> <p>4 certainly Mr. Ostfeld can.</p> <p>5 We are keeping this deposition open,</p> <p>6 because the witness has now testified during</p> <p>7 the deposition, potentially, to documents that</p> <p>8 she has not produced, including her invoices.</p> <p>9 It's not clear whether there were other</p> <p>10 documents that she hasn't produced. We'll come</p> <p>11 back to you on that, Ruben. But we are not</p> <p>12 closing this deposition until we get a complete</p> <p>13 record from Dr. Conti of the work she has done</p> <p>14 in response to the deposition notice.</p> <p>15 Now, I'll turn it -- turn it to</p> <p>16 Mr. Ostfeld to address your last point.</p> <p>17 MR. OSTFELD: I am putting into the</p> <p>18 record as an exhibit a document titled, "Expert</p> <p>19 Report of Rena Conti, Ph.D" from the case</p> <p>20 Blue Cross Blue Shield Association versus</p> <p>21 GlaxoSmithKline.</p> <p>22 This is taken from the public court</p> <p>23 file in that case. It has the court stamp at</p> <p>24 the top of it. It is document 286-2 from that</p> <p>25 court file. That is the only document that I</p>	<p style="text-align: right;">Page 209</p> <p>1 C E R T I F I C A T E</p> <p>2</p> <p>3 I, Jamie I. Moskowitz, a Shorthand</p> <p>4 (Stenotype) Reporter and Notary Public, do hereby</p> <p>5 certify that the foregoing Deposition, of the</p> <p>6 witness, RENA M. CONTI, Ph.D., taken at the time and</p> <p>7 place aforesaid, is a true and correct transcription</p> <p>8 of my shorthand notes.</p> <p>9 I further certify that I am neither</p> <p>10 counsel for nor related to any party to said action,</p> <p>11 nor in any way interested in the result or outcome</p> <p>12 thereof.</p> <p>13 IN WITNESS WHEREOF, I have hereunto set</p> <p>14 my hand this 17 day of February 2022.</p> <p>15</p> <p>16</p> <p>17  Jamie Ilyse Moskowitz License No. XI01658</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<p style="text-align: right;">Page 210</p> <p>1 RUBEN HONIK, ESQUIRE 2 ruben@honiklaw.com 3 February 17, 2022. 4 RE: In Re: Valsartan, Losartan, Et Al v. 5 2/11/2022, Rena Conti, PH.D (#5073516) 6 The above-referenced transcript is available for 7 review. 8 Within the applicable timeframe, the witness should 9 read the testimony to verify its accuracy. If there are 10 any changes, the witness should note those with the 11 reason, on the attached Errata Sheet. 12 The witness should sign the Acknowledgment of 13 Deponent and Errata and return to the deposing attorney. 14 Copies should be sent to all counsel, and to Veritext at 15 erratas-cs@veritext.com 16 17 Return completed errata within 30 days from 18 receipt of testimony. 19 If the witness fails to do so within the time 20 allotted, the transcript may be used as if signed. 21 22 Yours, 23 Veritext Legal Solutions 24 25</p>	<p style="text-align: right;">Page 212</p> <p>1 In Re: Valsartan, Losartan, Et Al v. 2 Rena Conti, PH.D (#5073516) 3 ACKNOWLEDGEMENT OF DEPONENT 4 I, Rena Conti, PH.D, do hereby declare that I 5 have read the foregoing transcript, I have made any 6 corrections, additions, or changes I deemed necessary as 7 noted above to be appended hereto, and that the same is 8 a true, correct and complete transcript of the testimony 9 given by me. 10 11 _____ 12 Rena Conti, PH.D Date 13 *If notary is required 14 SUBSCRIBED AND SWORN TO BEFORE ME THIS 15 _____ DAY OF _____, 20____. 16 17 18 _____ 19 NOTARY PUBLIC 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 211</p> <p>1 In Re: Valsartan, Losartan, Et Al v. 2 Rena Conti, PH.D (#5073516) 3 E R R A T A S H E E T 4 PAGE____ LINE____ CHANGE_____ 5 _____ 6 REASON_____ 7 PAGE____ LINE____ CHANGE_____ 8 _____ 9 REASON_____ 10 PAGE____ LINE____ CHANGE_____ 11 _____ 12 REASON_____ 13 PAGE____ LINE____ CHANGE_____ 14 _____ 15 REASON_____ 16 PAGE____ LINE____ CHANGE_____ 17 _____ 18 REASON_____ 19 PAGE____ LINE____ CHANGE_____ 20 _____ 21 REASON_____ 22 _____ 23 _____ 24 Rena Conti, PH.D Date 25</p>	

[& - 4:40]

Page 1

&	146:17 148:2	2/11/2022 210:5	74:9 80:23 83:23
& 2:16,20 3:17	1100 2:4	20 92:15 106:17	100:10 109:1
4:18 5:2,7,11 6:2	1154 209:16	212:15	112:22 113:8,14
6:13,18 7:8	11:03 76:2	20004 3:13 5:14	115:2 154:13
0	11:41 100:3	20006 4:20	169:14,16 171:19
0 88:14,20	11:46 100:8	2012 27:21 114:14	174:1 186:13
02109 6:15	11:49 100:9	143:10	3,741 19:11
07068 2:9	12 199:1 206:12	2018 25:13,15	30 3:6 13:11
07102 6:11	13 199:1	27:23 48:9 114:14	201:20 204:11
08540 5:21	14 199:2	156:22 157:5,18	210:17
1	1400 7:9	198:14	300 4:20
1 11:2 45:22 50:21	15 82:25 183:22	2019 27:23 48:9	31 159:23
54:21 55:20 56:8	199:3	202.452.7900 4:21	3100 4:5
65:24 66:2,3,10,16	1515 2:4	202.624.2500 5:15	312 7:9
67:9 68:11,17,23	15219 3:20 6:4	202.776.7800 3:14	312.456.1065 4:6
70:11,13 71:20	15th 6:10	2020 143:8	312.566.4803 7:6
72:23 73:2,12	16 199:18	2022 1:12 209:14	314.480.1500 4:16
74:3,15,19 78:4	17 200:2 209:14	210:3	317.236.1313 5:9
80:23 82:21 83:23	210:3	208 8:5	32 169:13
109:1 111:16	1700 4:20	21 5:20	32nd 3:19
115:2 154:2,12,16	17th 3:6	212.355.9500 2:18	33 146:17
159:20 168:5	18 8:3 200:3	212.415.9357 6:20	3600 4:11
192:18 201:19	182 10:6	214.855.8221 4:12	38th 6:4
206:20	19 200:3	215.979.1000 3:7	4
1,000 132:5 153:10	190 4:15	2200 4:11	4 15:6 94:24 95:1
10 12:13 92:13,18	19102 2:4	2220 7:5	95:2,8,12 111:17
136:24 201:19	19103 3:7	227 5:4	111:18 154:5,16
202:2 204:3,5,5	1st 27:21 48:8	23 156:8	154:18 198:24
100 2:13 6:10 10:5	2	230 7:5	412.263.4397 6:5
1000 3:13	2 20:18 21:7,11,11	250 2:17	412.560.3300 3:20
1001 5:14	50:22 54:25 55:21	267.435.1300 2:5	45202-4029 7:10
10013 2:18	56:12,19 58:19	27th 6:15	46204 5:9
10019-6119 6:20	59:4,12,14 65:25	28202 5:4	47 118:18
103 2:8	66:1,2,4,8,18	286-2 207:24	4:03 154:17
10:14 54:20	68:25 74:6,16,19	2875 1:2	4:04 155:16
10:20 54:19	78:6 80:23 83:23	2:45 195:7	4:05 155:20
10:22 54:24	84:22 100:4 109:1	3	4:34 183:6
10:55 75:24	115:2 201:19	3 20:19 21:9,12	4:40 183:9
11 1:12 5:8 10:4	206:21	28:11,23 55:21	
118:7 135:16	2,532,769 56:25	56:12 58:19 59:10	
		59:14 63:1 66:1	

[5 - added]

Page 2

5	62 48:23 73:8 74:11 63 27:24 28:10,19 48:1 84:14 173:20 173:21 63105 4:16 64 48:1 61:7 171:11,14 172:5,8 173:21 67 156:25	84 61:20	accounted 149:15 150:15 accounting 121:1 150:14 177:16 accounts 150:10 accrues 150:9 accuracy 210:9 accurate 45:7,8 accurately 43:23 193:1
5 15:5 27:7 62:8 78:23 82:20 85:8 85:11 92:15,17,18 92:23 107:17 109:8 111:21 162:4 198:10,13 50 116:15,21 500 132:4 504.524.5777 2:25 505 3:13 5073516 210:5 211:2 212:2 51 6:19 512.795.8686 2:14 513.698.5000 7:10 52nd 6:19 53 6:15 56 83:3 58 160:13 161:7 5:00 201:15 5:08 208:13	62 48:23 73:8 74:11 63 27:24 28:10,19 48:1 84:14 173:20 173:21 63105 4:16 64 48:1 61:7 171:11,14 172:5,8 173:21 67 156:25	9 92 118:2 973 6:11 973.228.9898 2:9 9:04 1:13 11:1 9th 3:13	accounted 149:15 150:15 accounting 121:1 150:14 177:16 accounts 150:10 accrues 150:9 accuracy 210:9 accurate 45:7,8 accurately 43:23 193:1
6	7 8:3 18:6,10 20:2 29:3 31:25 34:18 44:3 47:23 49:3 51:10 52:6,9 701 2:24 70130 2:24 704.444.3475 5:5 72 74:18 73 74:18 75 138:7,14 139:24 148:7 75201-7932 4:11 757.1100 6:11 76 110:15,20 77 4:5 776 69:23 78 32:4,7,9 49:8 171:6,10,12 78746 2:13 79 55:16,20 73:23	a a.m. 1:13 aa 33:21 34:5 abbreviation 33:21 34:5,10 ability 163:23 able 54:3 abraham 5:18 154:20,23 155:5 155:22,24 158:18 159:19 161:14 162:19 163:9,14 164:15,16 165:9 167:23 168:12 194:22 absolute 192:11 absolutely 75:2 118:12 189:16 academic 89:24 90:15 107:3 academy 199:14 access 40:11 42:22 107:12 accommodate 51:14 125:4 139:25 165:24 account 64:11 91:20 124:16 126:10 147:17 149:15 158:14 170:23 171:23 184:2 185:2,11	accounted 149:15 150:15 accounting 121:1 150:14 177:16 accounts 150:10 accrues 150:9 accuracy 210:9 accurate 45:7,8 accurately 43:23 193:1 acknowledgement 212:3 acknowledgment 210:12 acquire 123:6 174:9 181:13 182:1 acquired 26:19 130:5 acquiring 129:25 act 46:19 actavis 183:14 action 209:10 actions 1:5 active 172:11 activities 103:22 actual 17:6,7 30:22 31:19 62:2 63:3 64:18,19 65:17 91:3,21 96:3 118:24 131:20 133:20 162:8 166:18 ad 199:6,11,14 adam 2:7 adapt 197:16 202:15 adapted 196:9,14 add 70:21 added 174:6 199:4
6 13:11 89:7,10 94:12 95:2,18 60 27:7 28:18 48:23 73:7,7 75:18 77:8,23 78:3,9 156:6 160:6 201:20 204:12 600 4:15 5:4 6001 2:13 60601 4:5 60606 7:5 609.924.0808 5:21 61 48:23 75:18 77:8 78:7,9 617.213.7045 6:16	62 48:23 73:8 74:11 63 27:24 28:10,19 48:1 84:14 173:20 173:21 63105 4:16 64 48:1 61:7 171:11,14 172:5,8 173:21 67 156:25	9 92 118:2 973 6:11 973.228.9898 2:9 9:04 1:13 11:1 9th 3:13	accounted 149:15 150:15 accounting 121:1 150:14 177:16 accounts 150:10 accrues 150:9 accuracy 210:9 accurate 45:7,8 accurately 43:23 193:1 acknowledgement 212:3 acknowledgment 210:12 acquire 123:6 174:9 181:13 182:1 acquired 26:19 130:5 acquiring 129:25 act 46:19 actavis 183:14 action 209:10 actions 1:5 active 172:11 activities 103:22 actual 17:6,7 30:22 31:19 62:2 63:3 64:18,19 65:17 91:3,21 96:3 118:24 131:20 133:20 162:8 166:18 ad 199:6,11,14 adam 2:7 adapt 197:16 202:15 adapted 196:9,14 add 70:21 added 174:6 199:4

[adding - answered]

Page 3

adding 35:23	133:14 137:19,21	allocations 68:20	anal 147:21
addition 31:4	138:19 143:2	68:21,22	analyses 57:23
35:19 91:21	145:17,20 147:12	allotted 210:20	analysis 25:8 31:5
additional 37:9	167:6 168:6	allow 125:14	31:24 34:12,16
54:5 64:7,14	169:14	203:2	40:17 67:21 72:6
84:19 91:2 138:10	aggregated 26:7	allowed 25:22	103:3 156:21
155:9 185:10	35:20 44:16 64:2	135:25	157:9,16 158:9,24
187:3	147:6	alluded 39:18	163:19,21 164:2
additions 212:6	aggregation 35:22	alternatively	165:20 166:2,7,21
address 30:18	42:24 134:24	197:24	172:3 173:10
39:20 164:2 166:8	agnostic 184:17	america 40:21	186:10 188:2
205:22 207:16	ago 160:5	74:25	190:18,21 191:9
addressed 52:20	agree 60:7 144:21	america's 199:16	203:11
adjusted 185:9	144:23 152:7	americsource	analyst 51:23 54:3
adjustments 184:2	172:9 173:3 191:2	101:18	analysts 53:18
185:2,10	191:17	amerisourceberg...	analyzing 191:11
administration	agreed 167:24	7:11 101:16,19	andras 4:3
189:5	189:25 191:2,17	102:2,15,19	andrast 4:3
administrative	agreement 106:5	103:16 110:16	annual 132:7
166:9	180:8	111:7,11 112:1	144:2
admitted 207:1	agreements 106:3	113:11 132:6	answer 9:3 38:13
adulterated 27:23	ahead 15:19	143:10,25 144:10	39:2,3,12 45:3
48:9 186:1,9	166:22	151:10	46:20 58:17 60:2
188:14 189:7	aid 5:10 11:16	amount 15:22	60:17 66:13,20,23
190:2,6 191:3,18	41:19	23:12 35:13,21	69:6 71:4,5 75:12
193:5,23 194:9	al 198:15 210:4	39:23,24 57:4	76:12,18 79:12
adulteration	211:1 212:1	60:10,25 61:1	80:2 83:19 85:16
186:20 192:6,7,20	albertsons 4:21	63:9,10,19 65:4,14	86:1,13 88:12
advance 143:3	5:5 42:4,10,11,15	79:13 81:13 82:10	95:6 112:14 115:7
advisor 199:7,7,11	alek 3:5	82:23 83:1 89:4	120:3,14 125:14
199:14	alfano 6:2	127:8 128:4	126:16 128:22
ae 34:10	allegations 99:13	130:16 131:17,17	131:25 139:13,16
aforesaid 209:7	192:17	144:24 145:13	140:13 159:9
afternoon 154:21	alleged 27:11,13	176:10 178:9	161:9,18 174:17
154:22 155:23	157:6	181:4,7,13 182:1	178:14 179:1,20
182:21 183:12	allegedly 163:17	amounts 23:19	180:13,23 182:10
agents 167:9	166:11	49:16,18,21 50:13	184:7 197:4,25
aggregate 26:22	alleging 83:15	63:16,21 65:17,18	203:12,13,20
30:10,19 55:17	allocation 60:4	65:20 67:2 98:15	204:9
66:4,5 73:24,25	67:16,18,20 68:1,9	105:8 136:14	answered 26:18
74:4,7,9 118:22	69:4 70:23 71:1	147:12	53:14 69:12 72:25

[answered - attorneys]

Page 4

73:10 79:11 97:7 98:23 153:8 159:7 174:16 176:1 178:12 179:18 181:16 182:3,7,9 182:11 184:5,20 187:19 193:25 answering 175:2,7 196:21 answers 180:25 anticipate 151:19 anybody 178:22 apart 166:14 api 106:19 apologies 35:11 apologize 45:11 154:6 apparently 201:21 206:21 appear 201:24 appended 212:7 appendix 13:13 apples 59:8 applicable 210:8 applied 61:5 126:2 186:2,16,19 187:6 apply 47:10 149:11 190:13,21 applying 190:3 apportioned 109:3 apportionment 60:4 appreciate 51:1 68:5 163:13 appropriate 36:1 36:10 128:3 147:23 204:14 area 112:24 arizona 56:16,24 58:6,8,13,25	arrangement 98:2 arrangements 96:13,17 arrive 63:23 art 22:5 94:4 119:25 article 118:1,10 179:5 articles 202:8 aside 64:17 65:1 asked 27:16 39:5 47:2,11 53:13 72:5,24 76:23 79:10 83:21 97:6 98:22 113:9 114:10 115:20 122:16 130:15 140:5 152:4 153:7 168:4 174:16 175:25 176:6 178:12 179:17,25 181:15 182:2 184:4,19 186:8 187:19 188:3 192:2 193:24 196:25 201:23 202:10,14 203:19 203:24 204:1 asking 11:17 13:16,17,19 18:20 19:3 35:4 38:10 41:1 42:10 66:14 72:7 77:23 81:4,6 86:3 87:1 92:4 93:24 94:3,9 120:2 137:6,7 139:7,8 141:19 142:14 163:3 165:1 173:24 175:3 180:3 182:5 187:14 188:15	189:13 192:25 195:15,17,19 196:12,15,23,24 197:20 202:8 aslater 2:8 aspect 90:14 aspects 89:21 asserted 189:3 assess 47:25 132:12 assessed 96:23 assessing 70:25 assessment 71:7 assessments 25:11 assigned 161:13 assignment 71:3 71:12 159:12 assistance 195:23 associated 26:3 65:22 92:24 99:5 association 8:6 197:9,12,18 198:15 202:17,22 207:20 assume 27:16 32:14 36:10 39:8 68:12 69:19 70:8 83:21 113:9 114:10,24 115:20 186:9 188:6,11 assumed 79:3 157:15 assuming 32:16 43:16 98:8 143:13 144:9 198:24 assumption 33:25 38:19,21 143:16 157:9 188:1,1,4,15 189:2,8,12 192:19 193:4,22	assumptions 45:18 51:14 53:20 69:9 79:4 113:5 186:2 186:20 188:9 189:18,19,24 190:3 191:1,16 astonishingly 201:20 asymmetric 114:15 157:23 158:11 163:20 191:20 192:3 attached 181:6 202:9 206:22 210:11 attaching 208:1 attachment 15:5,7 41:25 44:19 45:22 46:16 47:3,24 53:4 56:14,21 58:4 62:3,4 63:4 64:19,20 109:9,12 109:17 111:14,16 111:18 attachments 44:7 44:19 47:19,21 51:8,12 52:16 74:3 attempt 71:17 attempted 116:10 attempting 203:18 attention 156:6 attestations 189:10 attested 189:4 attorney 38:11 112:11 125:11 183:18 210:13 attorneys 29:24 186:14
--	--	---	--

[attributable - c]

Page 5

attributable 160:1 166:10	60:18 64:21 65:24 73:1 75:17 76:3	bates 17:24 18:3	198:14,14 199:22
attribution 34:13	95:1 100:7,10	bazan 3:11	199:22 202:16,16
august 25:15	106:8 110:21	befuddlement 180:25	202:22,22 207:20 207:20
156:22 157:5,18	112:21,24 113:4	beginning 28:12	bockius 3:17
158:22 198:14	127:24 129:2	28:12 73:20 127:1	bold 2:13
aurobindo 3:21	130:22 154:18	142:3	bosick 6:2
69:21	155:21 162:1	begins 11:2 54:25	boston 6:15
austin 2:13 206:23	175:9 183:10	100:10 154:18	bottles 147:5
available 154:5	206:24 207:11	believe 97:15	bottom 69:24 146:17
158:12 161:22	background 27:3	111:14 156:19	boxes 147:8
166:25 172:14	105:19 132:19	173:4 180:1 181:3	brand 185:25 186:9 187:10,16
179:5 210:6	155:13 200:5	benefit 168:2	branded 99:4
avenue 4:11 5:14	backs 145:15	169:6 179:14,15	break 54:16,23 55:3 75:22 76:1,5
average 84:22,24	148:5,11 166:8,9	179:23 180:11	76:24,25,25 78:4
85:12,20 86:7,20	backup 18:20,22	203:25	99:23 100:6 150:2 154:15 183:4,8
87:12 88:2,2,4,9	19:3,7,25 20:15	benefits 93:11	breaking 77:9,16
89:12 94:16 95:21	21:5 118:6 168:4	bennett 24:21	breaks 76:6,16 108:24
averages 119:5,5	bad 22:7,8 54:10	25:17 31:21	bresnahan 5:12
award 65:12	bag 91:11,17 93:7	berne 7:8	brick 32:14
aware 13:22 33:19	barcode 136:2,7	bernstein 2:16	brief 168:8
33:20,23 40:23	bargaining 151:12	best 101:6 132:20	briefly 155:2
42:25 43:10 92:22	barnes 5:7	176:4	broad 17:13
123:19,23 124:1	base 106:19 129:9	beyond 70:19	btlaw.com 5:8
135:11 148:20	131:9	86:23 139:15	buchanan 4:18 5:2
181:11,21	based 29:21 51:9	145:4 186:21	build 53:18
awash 135:10	53:19 63:25 65:3	187:19 204:11	bully 183:18
awsmolij 3:5	86:16 126:5	big 150:7 203:22	bundle 152:10
b	131:20 134:18	bill 78:23 166:8	burke 206:23
b 3:6 5:3 7:3 8:1	184:22	bills 25:3,12,13	business 102:4 132:10 146:6
13:11,13 15:5,19	bases 68:16	bily 7:13	busy 108:16
18:17,23 19:6	basic 84:17 129:10	bipc.com 4:19 5:3	c
29:12 41:25 109:9	141:20	bit 19:14 108:13	c 2:1,23 3:1 4:1 5:1
109:12,17 111:14	basically 49:1	111:13 120:25	6:1 7:1 31:25 61:7
111:16,18 123:14	124:6 147:10	123:12 151:17	209:1,1
132:14	basis 31:4 44:5	bizarre 92:22	
back 11:2 27:6	60:19 70:17	blackwell 4:14	
28:11 29:2 34:17	192:19 193:4,21	168:20,23	
35:25 36:2 47:25	batch 118:24	blank 33:10	
49:6 51:16 53:21	133:19	blue 8:5,6 197:9,9	
54:11,25 58:20		197:12,12,18,18	

[c.whiteley - charge]

Page 6

c.whiteley 2:21	185:8	care 121:25	caveat 47:8,11
cabraser 2:16	call 17:9 119:11	carlo 5:19	cdehart 5:20
calculate 47:16	120:13 133:24	carolina 5:4	center 6:10 201:5
49:12 54:12 72:5	called 47:23	carondelet 4:15	centre 3:19 6:4
116:11 125:25	109:19 111:19	carve 146:13	cents 98:17
133:3,10 135:8	170:23	case 12:7,24 13:7	cert 168:8
140:5 161:7	calls 45:10 58:16	14:20 29:10,14	certain 96:18,18
175:22 177:10,20	67:15 83:18 85:25	31:3 37:12 41:12	96:19 105:22,24
178:8 181:3	86:11 122:25	42:9 60:22 71:13	115:20 145:18
calculated 58:24	124:4 126:14	74:22 99:13,14	certainly 103:13
59:1 66:8 73:2	139:3 145:7 184:5	100:20 105:1	106:25 196:19
125:23 167:19,22	camp 2:24	107:5 109:19,22	199:3 207:4 208:3
173:25 177:1	campbell 5:13	109:24 110:3	certified 1:14,15
183:25 185:16	10:5 100:12,14,18	111:3 112:2	certify 209:5,9
calculating 61:21	100:25 101:4,7,21	114:22 115:5,23	cetera 137:24
86:7,16 90:3	104:21 106:1	118:9,14 121:18	151:18 190:10
115:24 116:5	107:15 109:6,10	135:22,22 149:1	192:7
122:17 124:15	110:22 112:20,23	151:24 152:17	cgannon 6:8
138:7 139:9	113:1 114:5,21	167:17 169:9	cgmp 190:7
156:14	115:15 116:8,14	171:1 176:13	199:20 200:8
calculation 17:13	116:16 119:14	185:15 186:11	chain 37:7 103:6
20:13,24 21:13	121:7 122:7,9	188:2 193:6	106:21 114:18,20
24:24 51:22,24	123:15 124:13	195:11,16,20,21	117:9,17 120:1,10
53:24 56:23 59:6	125:6,19 126:22	196:1,2,9,10,11,13	120:17 121:15
62:2 65:10 66:16	127:23 128:15	196:14,16,17	135:2 136:5
66:17 87:16	129:1,14 130:8,19	197:11,15,17,20	142:13 145:21
106:14 125:16	130:21,24 132:22	197:22 198:3,17	164:8,19 172:17
126:6 127:18	135:19 138:13	199:21,23,25	change 51:5 54:4,5
129:2,9 130:7,9	139:6 140:3,16,21	200:8,9 201:5	152:24 198:24
140:8,24 160:4,13	140:22 141:3,22	202:18 203:10	199:17 211:4,7,10
165:22,23 167:18	142:1,4 144:20	207:1,19,23 208:5	211:13,16,19
169:17 171:8,16	146:1	cases 31:9 116:9	changed 53:3
187:6	capital 94:21 99:7	199:24	191:1 199:3,4
calculations 17:6	captured 64:13	cash 77:10,18	200:2,3
17:8 21:6 44:5	card 78:19,24	78:11,14,20,21,21	changes 210:10
53:19 54:6 58:5,7	cardinal 5:15	79:2,6,9 80:17,17	212:6
63:3 66:10 98:19	101:15,23 102:2	81:10,15,17,20,20	changing 75:19
116:4 124:8	102:15,20 103:16	81:24,24 166:9	characterization
138:23 149:13	111:6,11 112:1	categories 48:17	60:13
162:24 163:13	113:12 132:6	category 142:16	charge 16:5 82:23
184:12,13,16	143:11,17,25		91:13 145:15

[charge - concluded]

Page 7

148:5,11 166:8 charged 23:21 97:11 charlotte 5:4 charts 181:6 cheap 146:10 check 13:13,14 20:10,24 21:3 29:7 31:11 33:13 43:25 79:4 108:15 157:2 checking 20:11 checks 31:15 cherry 201:6 chewing 71:16 chicago 4:5 7:5 15:24 16:4,12 104:6 chosen 204:18 christine 6:8 christopher 5:3 christopher.henry 5:3 cincinnati 7:10 circumstances 181:12,23 cite 175:14,21 cited 12:17 claim 39:23 49:22 64:2,25 123:22 claiming 65:14 claims 15:8,14,18 17:10,11,24 20:13 21:20 22:1,3,12 23:5 26:15 29:19 29:21 30:22 31:20 32:18 33:9,17 36:12,19,21 37:17 39:8 40:24 41:2 41:15 42:7 43:5 46:19 48:21 49:15	49:15 50:8,9,15,17 50:22 57:6 59:12 65:3,19 67:1,3 71:11 74:11 171:17 clarification 169:11 170:21 clarify 86:4 128:1 180:5 clarifying 36:7 class 12:24 13:2 77:8,15 85:22 86:10,23 101:10 101:11 121:12 122:2,5 123:4 136:1,4 168:8 classes 164:4 clawed 206:24 clean 31:10 clear 54:2 74:19 160:23 176:5 178:12 207:9 clearer 95:23 clearly 45:23 57:21 94:1 95:24 clerk 91:11 client 38:11 client's 185:15 clients 193:23 clinics 117:15 121:24 clipping 202:8 close 101:5 closed 102:10 closely 151:25 closing 207:12 coan 6:14 code 22:17 25:7,20 26:21 29:14 35:5 40:14 59:7 119:6 133:19 186:24	codes 24:10 29:21 29:25 30:5 50:10 51:21 54:5 57:13 118:22 186:15 187:2,3 coleen 3:4 collaboration 104:17 collaborative 16:5 16:6 collect 37:2 40:20 collected 17:14 96:10 collecting 16:23 collectively 113:12 color 180:21 column 29:9,12 31:25 34:20 35:8 35:8,12 68:11 70:12,13 72:23 columns 19:16 29:6 come 127:6 162:3 172:20 207:10 comes 123:19 comfortable 34:14 53:16 189:18 coming 110:2 188:16 commencing 1:13 commentary 180:21 comments 164:9 180:15 commercial 23:24 96:25 committed 83:16 committee 199:8 199:15 commonly 99:11	communicated 188:24 communication 38:19 76:10 communications 76:6,22 77:1 194:3 companies 12:24 42:21,23 131:6,10 132:5,9 153:15 company 151:8 153:10 compare 197:25 200:13,20 202:21 compared 64:19 comparing 59:8 complaint 27:17 28:13,24 83:22 115:2 186:14 192:17 193:6,20 complete 53:22 200:11 203:11 207:12 212:8 completed 210:17 completely 71:11 164:21 completion 31:11 compliant 190:7 components 105:3 compound 39:6 166:13 195:13 computer 106:9 132:3 155:14 concept 42:25 146:23 152:19 concern 86:15 concerned 206:16 concerns 67:21 concluded 199:25 208:10,12
--	---	---	--

[concludes - copy]

Page 8

concludes 204:19	consideration 92:5	106:24 119:25	116:17 122:11
concluding 11:8	considerations	121:20 133:1	154:4,21 155:23
205:4	146:13	157:10 158:1	159:4 162:20
conclusion 45:10	considered 70:1,2	160:20 162:9,18	168:4 169:15
45:17 58:16 60:1	138:21 139:22	165:16 166:16	183:12,19 200:23
67:15 69:2 83:18	148:8 167:3 173:6	171:16 172:19	203:5,10,19
85:25 86:12	174:11,11	176:13,16 177:4	205:13,25 206:18
119:11 120:13	considering 37:4	189:6 191:25	207:13,19 208:6
126:14 139:3	consistent 156:24	192:3	209:6 210:5 211:2
145:8 184:6	consultant 199:5	contain 30:12 42:7	211:24 212:2,4,12
concomitantly	consume 168:13	53:22 136:8 157:6	conti's 201:22
168:7	consumed 159:16	contained 33:5,6	continue 146:21
concrete 82:25	consumer 19:18	52:5 147:12	continues 148:3
condition 192:2	23:22 35:10,12	157:18 173:25	contours 189:15
conduct 114:25	39:19 40:2,16	193:6	contract 143:14
115:5	41:4 43:7 46:18	contaminated	144:9,11,12
conducted 166:2	49:16,21 50:12	157:11,12 159:17	150:22 151:9
confer 13:23	56:15,24 58:12	163:25 165:25	152:6 153:1
154:11	59:17 60:23 61:2	166:11	contracted 143:2
conferences 102:9	63:15 67:10 68:10	contamination	contracting 143:7
103:17	70:13 71:20 72:9	114:16 157:25	143:9
confidential 1:8	72:11,22 77:8,15	158:16 188:23	contracts 143:1,4
70:2 76:9 166:25	85:11 89:11 92:7	194:4,5	143:17 145:2,5,11
confidentiality	93:9,9 94:15,17,18	content 144:17	145:23 146:3,5
106:2,5 125:12	117:14 119:8	contents 10:1	151:22 152:9,16
confine 25:22	120:11 159:13	33:15	152:20,21,21,24
confined 156:21	160:1 161:25	context 101:22	153:2,24
confirm 13:6 35:4	163:5,12,21 164:4	102:1 105:11	contrast 200:21
37:16 38:20 46:4	176:10 192:9	117:8 129:17	contribute 88:14
111:24 119:7,20	consumers 22:15	140:6,15,17,23	controversial
confirmed 68:18	30:10 48:4 50:6	contexts 101:16	57:17 77:5 171:5
confirms 38:24	63:22 65:13 67:2	conti 1:11 2:5 8:3	convenient 201:7
confused 185:6	67:9,10 69:22	8:5,5 10:2 11:15	conversation
conjunction 163:1	70:12,15 71:21	15:5 18:6,10 20:2	148:12
conlee 2:21	77:20 84:23 85:3	27:7 29:3 44:3	conversations
consented 177:5	85:13,21 86:8,9,9	47:23 49:3 51:10	135:7,21
consequently	86:16,21 87:13	55:3 68:19 70:24	copied 196:9,13
128:3 133:2	88:3,5,10,24 89:9	76:5 87:22 100:13	copies 210:14
consider 43:4	89:13 90:10,17	100:22 101:8	copy 197:16
137:2,15 148:5	94:12 95:3,14,18	109:8,11 110:23	202:15
165:20	95:20,22 97:11,20	111:18 113:2	

[corporation - court]

Page 9

corporation 4:12 110:16	82:8 85:12,21 86:7,18,20 87:13	6:16,21 7:6,11 11:8,10 13:24	107:13 110:4 146:6 192:14
corporations 144:2	88:2,3 89:12,14 90:10,16,19,24,25	36:9,16,18 37:8,15 38:9,22 39:7 45:1	coursework 101:10,11
correct 12:14 13:8 13:9,16 15:11 24:14 25:4,13,14 29:8,10,15 32:1,3 32:15 35:16,17,19 35:23 42:6 44:4 44:14,17 45:1,4,7 45:19 47:10,24 49:3 56:4,12 57:7 57:8 58:7,14 60:10,15 62:22 63:2,9 65:5 66:11 67:11 68:20 79:20 84:6 85:9,10 108:2 111:22,23 112:2,3 114:9 115:5,8,8 116:2 119:9,22 120:1,4,5 121:9 127:3 128:14,19 132:1,2 132:3 146:23 149:9 152:24 156:17,18,22,23 157:2 158:24,25 160:8 169:20 170:19 184:18 186:3,11 190:10 191:22 192:20 193:7 198:20,21 209:7 212:8	91:9,10,11,14,21 92:6 93:2,6,7,7,10 93:14,19,20,22,25 94:7,11,14,17,18 94:20,23 95:1,2,12 95:13,13,14,16,18 95:21 98:20,25 99:2 126:25 127:10,19 129:24 133:20 134:8,9 138:1 145:2 146:16 147:24 148:2,2,4,9 149:4 149:12,25 150:2 150:12 173:11,15 174:9,12 175:23 175:24 176:8,19 177:2,11,17	45:18,24 46:3,13 46:19,24 47:7,16 50:11 76:10,14 104:2 112:8 113:9 115:14 122:17 124:24 125:3 126:15,20 132:18 138:23 140:2 149:2,16 154:10 161:4 163:10 166:5 168:7,17 184:23 185:1 186:15,24 187:1 188:3 193:11,14 193:16 201:18 203:18 205:14,16 209:10 210:14	court 1:1,14 11:12 14:5,7 16:1,9 17:18 23:6 24:16 34:1 45:2 57:11 59:20 61:23 64:4 66:21 67:17,19 69:4,12 71:8 75:8 77:11,15 80:13 81:22 91:5,8 96:14 97:22 100:16,25 101:2 101:17,20 104:15 105:7,13 107:10 110:18 112:17 113:20 114:19 115:10 120:19 121:4 125:1,3 126:20 128:12,23 129:12,15 130:1 131:24 132:15 135:13 138:9,11 138:23 140:1,19 141:25 149:3,6,17 149:22 150:18 153:16,19,21 158:4 162:13,16 164:13 165:6 166:5 167:20 169:2,4 170:8 171:13 178:1,21 182:22,25 185:1 185:12,18,21 193:13,18 194:18 194:23 199:10 203:7 204:22,25 206:5 207:22,23 207:25 208:2,5
corrections 212:6 correctly 94:5 correspondence 13:24 103:20 corresponds 44:8 cost 48:6 50:4 64:11 65:20,20	costco 132:8 144:3 costs 61:12,13,16 64:7,14 84:18,22 88:22,23 89:8,8,25 90:4,5 91:2,18,21 92:1,15,17 93:2,2 93:23 94:10 95:9 95:9,10,10,17 99:5 99:7 130:6 135:12 138:10 149:18,19 149:20 150:2,4,5,5 150:9,10,11,17 173:23 174:20 176:20 177:4,6,7 costumer 143:20 counsel 2:5,10,14 2:19,25 3:8,14,21 4:6,12,17,21 5:5 5:10,15,22 6:5,12	counsel's 127:14 127:17 count 158:14 counted 43:23 59:4 149:23 150:20 counter 63:22 79:14 91:12,17 94:22 166:19 167:13 counterfeit 135:5 counting 97:9 158:11 couple 27:18 68:16 77:3 99:10 103:10 108:16 123:17 131:2,2 132:23 course 31:2,8 102:3 103:1	

[cover - davis]

Page 10

cover 143:4 195:4	143:19 144:5	71:20 72:10,23	42:6,7,11,15,16,23
covered 74:21	145:22	73:12,24 74:1,4,7	43:1,5,7,11,12,16
covers 97:24	cut 38:3,4 155:1,2	74:10,13,16,16	43:17,20,24,25
cpudt 95:21	175:5	84:1,3,5 106:14	44:12 49:15,23
crazy 87:8	cv 16:22 197:14,21	115:25 116:11	51:16 52:1,1,12,13
create 29:19 47:20	198:4,6,7,10 200:1	122:18 124:1,15	52:15,18 53:6,17
51:7,11 52:16	201:22	125:22 126:24	53:20,22 54:10,10
53:6 180:15	cvs 5:10 11:16	127:5,12,18 128:3	54:11 57:6,23
created 24:15	15:23 16:16 41:19	128:10 129:3,10	60:9 65:3,10
creation 21:19,25	42:4,15,15 56:16	130:10 133:4,10	66:15 67:5 81:9
credit 78:19,24	56:24 57:7 58:6	156:14,21 158:23	89:19 96:1,4
criteria 161:11	58:13 63:5,6,15,25	159:12 160:1,12	102:14 104:6,12
162:5	64:8,25,25 65:3	160:14 161:8	104:19,22,24
critical 25:8	75:1 98:5 99:13	162:1 163:5,12,12	105:4 106:3,13
cross 8:6 122:3	170:18 172:15	164:2,3 165:20,21	107:9,11 110:17
197:9,12,18	cwhill 3:4	166:4,7,17 167:19	110:19 111:19,25
198:14 199:22	d	167:22 168:6	112:4,19 122:4
202:16,22 207:20	d 4:14,19 6:18 7:8	169:15,16 181:3,7	124:21,23 125:16
crowell 5:11	34:20 80:22 84:23	183:25 184:3	126:5 132:12
crowell.com 5:12	85:3,13 88:24	185:16	133:3,9,17,20,23
5:13	89:11,12 95:14,19	dan 100:14	133:25 134:2,6
cs 210:15	95:22	dana 3:6	135:10,23 147:21
culbertson 6:13	d'lesli 4:10	daniel 5:13	147:25 148:24
current 194:13	d.stanoch 2:22	data 14:17,17 15:7	160:19 161:2,10
198:25 201:25	daily 26:1 107:13	15:8,14,14,18,22	161:21,23 162:2
currently 13:1	110:5	16:4,5,14,21,24	163:6 166:1,20,24
199:6,13	dallas 4:11	17:9,10,11,24	167:11,11 168:4
curve 187:10,12	damage 37:13	20:15 21:19,20,23	168:10 170:6,10
187:17 190:1,11	57:8 66:7 122:1	21:24,24 22:1,3,3	170:24 173:13
191:10,11,12	124:8 165:23	22:3,10,12,14,19	174:9,10 176:15
customer 23:19	184:12,18 185:7	23:5,12 25:19	177:14,23 186:16
30:18 35:8 41:2,3	damages 8:3 18:7	26:10,15 29:19,21	dataset 50:10
41:4,5,6,7 61:10	18:18 20:4 21:13	30:8,19,22 31:10	53:21
92:14 141:13,16	44:4 48:18 49:9	31:11,15,16,20	datasets 49:15,22
141:21,24 142:3,5	49:10,13,14 55:8	33:9,17 34:15	date 25:9 30:16
142:10,14,15	55:15,17 56:8,9,16	36:10,12,19,21	40:1 69:20 156:15
144:14 145:6	56:24 58:9,12,13	37:2,4,4,9,11,16	211:24 212:12
150:24,25	58:21,24 59:5,18	37:17 38:4 39:8	dates 25:17
customers 141:7,9	66:4,5,6 67:9,10	39:15,17 40:7,11	david 2:22
141:11 142:12,18	67:12 68:8,11,13	40:19,24 41:2,2,3	davis 2:11,12 4:10
142:22,23 143:15	70:12,13,15,25	41:7,10,15,17,22	

[day - different]

Page 11

day 23:15 31:18 93:1 106:16 118:8 135:16,17 172:16 209:14 212:15 days 103:11 210:17 dc 3:13 4:20 5:14 dcampbell 5:13 deal 99:8 dealing 151:9 dean 154:7 decide 127:4 149:7 150:19 185:13 decided 137:17 declaration 13:15 74:3 110:9 114:23 115:4 195:11,12 195:16,20,21,25 196:9,13 197:22 202:18 declarations 13:16 110:25 declare 212:4 deductions 61:24 138:9 deduplicated 55:16,18 58:22 74:4,7,9,16,18 deduplication 55:7,24 56:19 58:20 59:11,13 73:19 deemed 212:6 defendant 3:21 4:6,17,21 5:5,15 6:12,16,21 7:6,11 27:21 36:13 37:19 39:10 41:18,19,22 43:6,8 48:2,7 49:8 49:12,14,22 50:7,8 50:13 58:10 59:19	66:9,10 73:12 74:1,5,8,10,13 99:14 103:12 110:15 113:13 122:18 131:1,5 133:4,5 169:9,18 defendants 3:8,14 5:22 6:5 11:19 12:24 13:25 15:10 18:2 27:15 29:10 29:13 36:11 37:17 38:23 41:12 42:9 44:6 67:12 68:13 74:22 83:16 91:22 110:6 113:11 126:7 128:6,17 170:25 183:14 202:1 defense 168:7 defenses 110:7 defer 149:6,21 150:18 define 22:2 72:18 85:2 94:14 95:1 95:16 194:11 defined 25:20 27:19 48:5 89:8 92:6 93:25 94:1 95:12,13 98:24 126:25 173:23 defining 89:25 definitely 58:3 199:18 200:3 definition 81:4 88:13 93:22 94:7 107:4 136:3 146:25 161:19 162:7 166:16 167:11 173:14 176:12 184:11	dehart 5:19 delete 205:15,15 delineated 186:22 delineates 81:9,16 delineation 79:25 deloitte 117:25 118:6,6 delta 123:9 133:15 demand 191:10,11 denominator 88:18,19 department 150:9 depending 124:2 150:21 depends 98:1,18 140:14,14 145:3 152:12,13 deponent 210:13 212:3 deponents 13:21 depose 33:15 deposing 210:13 deposition 1:11 11:25 12:21 13:10 13:20 111:9 170:13 175:6 198:20 200:15 203:17 204:19 205:5,7,13,17 206:11 207:5,7,12 207:14 208:12 209:5 depositions 13:5,6 13:11,20 derive 33:3 35:12 derived 19:1 34:21 35:5 47:18 deriving 87:12 described 49:19 73:7 74:11 128:16 133:5 186:22	description 8:2 9:7 descriptions 125:7 desk 106:9 detail 84:19 95:17 125:17,20 details 73:25 115:20 determination 139:14 determinations 68:1 69:11 determine 84:21 88:22 157:4 201:23 determined 79:9 140:2 determines 98:6 determining 137:3 develop 122:17 deviations 144:16 dictate 144:8 145:12 151:15 dictates 144:10 differ 21:11 126:3 133:11 143:5,6,10 144:13 145:5,24 146:11 151:17 difference 20:19 50:14 79:23 81:6 81:19 82:15 123:5 125:21 131:16 137:22 differences 105:12 105:15 124:17 125:8 126:10 147:18 151:21 184:2 185:3 different 20:18 36:8 41:9 51:5,6 54:10 64:15 65:13
---	--	--	--

[different - dropped]

Page 12

69:18 74:17 78:5 87:17 90:6 96:13 96:17 117:10,11 117:13,14,17 119:25 121:15 123:20,24 126:6,8 133:21 141:7,7,8,9 141:17 142:22,23 142:24 143:8 145:12 147:9,11 149:1 150:12 158:15 175:12 184:2 188:1,5 differently 178:14 differs 133:4 difficult 21:2 diovan 185:17,18 186:9 187:10,16 dir 96:6,9,20,22 direct 55:11,12 directed 69:4 78:8 direction 31:6 directly 89:5 92:13 114:7 119:21 121:2 167:6 disaggregated 26:10 147:23 disagree 60:12 discernable 161:2 discounted 148:16 discounts 61:4 145:17 148:19 149:11 166:9,15 167:15,16 discovery 14:3,14 discussed 28:23 29:22 31:22 40:12 49:25 61:20 83:22 186:13,18	discusses 32:12 discussing 102:10 discussion 104:8 155:18 168:13 201:16 discussions 37:10 194:5 dispense 63:12 89:13 92:25 95:22 172:9 dispensed 23:15 24:1 32:24 37:22 40:2,20 41:6,11 42:8 65:21 85:23 89:6 106:24 160:21 171:25 172:19 dispensing 16:24 21:18,24 22:3,18 22:19 23:21 30:14 30:17 36:22 37:3 37:6 39:16 40:3 42:23 49:24 50:4 50:5 61:14,16 63:21 64:8,12,13 88:23 89:9,14,17 89:18 90:5,10,16 90:20,24 91:3,18 91:21 92:7,15,17 92:23 93:2,14,23 93:25 94:7,12,15 94:17,18,20 95:3 95:10,14,17,25 97:5,10,12,15,19 97:20,25 98:1,6,14 98:25 99:1,6 170:4,6,24 171:15 171:22 172:14 173:12 174:7,20 176:20 177:6,7,17 179:13 180:1,5,7	180:10 distinction 20:7 28:24 81:1,16 82:12 distinguishes 81:9 distortion 203:22 distributer 164:18 distributers 99:12 106:21 118:2,8,20 119:3 distribution 121:15 131:6 164:20 distributor 164:8 164:12,23,23 165:2,13,15 distributors 105:23 107:8 116:25 117:7,12 117:21 district 1:1,1 dlesli.davis 4:10 doctor 11:4 110:19 182:21 195:2 doctor's 168:14 document 1:4 19:22 23:4,8 38:22 196:1 197:25 202:1 204:1,2 206:25 207:18,24,25 documents 9:6 11:23 13:14 15:9 17:23 18:1,1,21 19:4 106:8,9 109:20,23,23 110:2 111:5 131:20 207:7,10 doing 31:5,9,18 49:1 53:11 88:4	116:4 147:25 158:9 180:19,20 205:6 dollar 98:17 169:15,21 door 102:10 dorner 3:12 dorsey 6:18 dorsey.com 6:19 dose 172:11 double 20:10,11 20:24 21:3 29:7 31:11,15 108:14 157:2 downstream 30:3 136:5 142:11,17 143:15 144:5 153:1,25 189:5 dozens 107:22 dr 11:15 55:3 68:19 70:24 76:5 87:22 100:13,22 101:8 109:8,11 110:23 111:18 113:2 116:17 122:11 154:4,21 155:23 159:4 162:20 168:4 169:15 183:12,19 200:23 201:22 203:5,10,19 205:13,25 206:18 207:13 draft 195:22 draw 156:5 drew 3:12 drive 4:5 driven 144:18 drop 121:2 dropped 139:22
---	---	---	---

[drug - established]

Page 13

drug 91:16,22,23 92:12,13,14,23 93:4,6,12,13 94:22 98:16 105:5 118:22 131:14 135:9 169:23 173:4 174:12 181:14 182:1 189:5 drugs 5:22 23:15 28:21 37:6,24 51:20 64:2 67:4 75:3 79:15 82:8 86:17 97:19 99:6 103:22 104:24,25 105:22 106:18 113:23 114:3 116:7,23 117:5,10 117:18 118:5 120:22 121:12 123:6 126:3 127:9 131:14 132:16 135:4 139:10 140:6 146:10 154:24 155:7,25 162:10 172:14,20 174:10 180:10 186:1 190:3 191:4 191:19 199:6 dt 81:24 95:13,13 95:18 dtdorner 3:12 duane 3:2,10 duanemorris.com 3:3,4,5,11,12 due 17:17,19	eabraham 5:19 earlier 22:1 97:18 102:22 104:4 111:15 133:24 134:3,9 147:16 148:12 156:20 170:4,11,13 180:1 180:4 181:3 193:1 193:3 194:16,24 196:14 early 37:11 112:22 easiest 49:6 easily 138:10,11 161:2 eastern 1:13 easy 124:6 echo 14:8 economic 84:1 191:4,19,24 192:12 economics 16:7 economist 46:9 47:13 139:9,20 economist's 70:19 ecosystem 102:6 102:18 effect 93:13 effectively 156:14 effects 93:11 efficacy 190:9 eisenhower 2:8 either 77:14 102:24 111:6,25 137:25 148:8 149:1,4 164:4 172:10 198:1	146:22 ellie 4:9 ellie.norris 4:9 email 103:20 employee 110:13 149:19 150:4 employees 135:22 encountered 34:8 ended 204:10 ends 28:10 54:21 100:4 154:13 engage 68:6 engineering 199:8 199:15 enormous 75:2 enrichment 20:5 20:13,17 21:6,12 27:19 47:6 48:3 48:18 49:9,13 50:22 58:5,7,13 59:5,9,18 60:20 61:6,25 62:21 63:24 64:11,24 65:19 74:10 84:5 84:12 115:18,25 116:6,11 122:18 122:23 123:20,22 123:24 124:10,15 125:23 126:1,24 127:5,8,13,16,18 128:11,14 129:3 129:10 130:10 131:12 133:4,10 149:13 169:15,16 171:8,17 184:10 ensure 53:21 135:4 entails 61:8 enter 136:1 entering 136:4 152:9	entire 14:24 136:2 195:12,16,20 entirely 202:9 entirety 30:15 66:24 entities 96:8 103:5 131:8 entitled 20:4 59:17 entity 19:17 144:7 144:18 151:11 entry 108:25 enumerated 28:23 37:14 63:1 171:18 186:13 epedigree 134:5 135:1 147:15 equal 57:4 63:8,10 63:18 65:4 equals 80:22 81:24 84:2 95:13,19 equation 160:25 eric 5:18 154:23 155:2,24 168:2 194:22 errata 210:11,13 210:17 erratas 210:15 especially 172:20 esquire 2:3,7,12 2:16,21,22,23 3:3 3:4,5,6,11,12,17 3:18 4:3,4,9,10,14 4:19 5:3,7,12,13 5:17,18,19 6:3,8,9 6:14,18 7:3,4,8 210:1 essentially 115:23 126:24 established 38:25 41:25 46:13 48:12 140:12
e	elaborate 73:15		
e 2:1,1 3:1,1,11 4:1 4:1,4 5:1,1,17 6:1 6:1 7:1,1 8:1 35:8 209:1,1 211:3,3,3	electronic 15:7 111:19,25 112:4 elements 123:20 136:10,11,12		

[estimate - file]

Page 14

estimate 75:5,10 estimates 20:17 estimation 74:20 122:1 et 137:24 151:18 190:10 192:7 198:15 210:4 211:1 212:1 events 110:5 evidence 207:1 exact 48:20 58:6 192:5 exactly 50:24 59:2 117:24 132:12 189:15 192:8 examination 10:3 11:14 100:12 182:20 example 55:9 56:3 56:4,10 108:24 138:15 143:17 144:24 149:11,19 151:10 164:25 172:15 examples 56:11 exceeded 201:18 202:2 excel 8:4 18:7,19 24:23,24 33:9,16 49:2 exclude 29:20 30:6 49:17 191:14 excluded 34:2,3 34:12 exclusion 20:20 161:11 162:6 exclusions 51:15 excuse 28:16 68:15 91:6 94:4 176:23 179:9 197:23 203:1,1,25	executives 103:21 exercise 147:20 200:11 exforge 185:17,20 exhibit 8:2 15:5 18:6,10,17,23 19:6 19:25 20:2 25:1 27:7 29:3 31:25 34:18 44:3 47:23 49:3 51:10 52:6,9 62:5,7,8 107:17 109:8 202:3 204:10 206:22 207:18 208:1,3,6 exhibits 10:7 13:10,20 44:9 202:9 exist 145:1 149:4 202:2 existence 179:22 expand 84:18 expect 31:14 124:22 144:11 146:11 151:14 198:25 expecting 123:18 expenditure 77:16 expenditures 27:8 77:9 expense 182:1 experience 106:12 172:8 experienced 130:3 expert 8:5 46:10 59:25 116:10 139:8 156:2 197:8 197:17 202:16 207:18 expertise 51:7 expired 203:15	explain 48:2 49:11 58:20 73:23 87:23 97:4 171:15 174:12 explained 48:1,22 49:7 95:11 explanation 73:2 express 4:17 42:5 156:13 168:24 expressed 27:9 70:20 85:8 89:9 95:18 136:24 137:21 extent 16:22 38:10 45:10 58:16 59:25 67:15 76:9 83:18 85:25 122:25 124:4 125:11 126:1,14 139:3 149:25 154:3 157:25 158:19 167:8 184:5 f f 209:1 fact 12:23 117:3 170:23 171:23 189:11 199:19 204:3 factor 88:2 98:20 138:2 139:11 factors 139:21 faculty 16:8,10,11 16:15 17:9 fails 210:19 fair 15:22 22:6 36:6 157:15 162:24 165:18 fairness 201:1 falanga 6:7 falkenberg 7:2	falkenbergives.c... 7:3,4 fall 74:11 88:19 familiar 22:4 181:22 far 125:9 131:21 206:15 fast 165:8 fault 165:9 favorite 98:5 fda 29:17,25 188:25 190:9 194:2,17,25 fda's 199:5 february 1:12 209:14 210:3 fee 22:18 30:14 40:3 61:14 63:12 63:21 64:13 89:17 89:18 92:23 95:25 97:5,10,10,16,19 98:6,14,25 99:6 173:12 174:7,20 179:13 180:5,7 feel 34:14 53:16 179:4 fees 23:2,21 36:22 49:24 50:4 96:6,9 96:20,22,22 97:20 97:25 98:1 99:1 149:12,12 166:9 170:5,24 171:15 171:22 fhs 6:3 field 33:10,18,22 94:5 107:1 135:10 fields 31:12,13 figure 22:9 87:12 figures 169:15,21 file 18:7 21:25 24:7,23 26:16
--	--	--	--

[file - function]

Page 15

29:3,19 33:4 44:5 44:8,22,25 51:10 52:11,16,21 53:5 53:12 207:23,25 208:5 files 168:9 filing 69:21 70:9 fill 30:8 106:19 filled 36:12 37:18 39:9 82:7 156:22 157:17 filling 90:25 fills 23:1,22 29:20 30:7,11,13 33:3 36:3,4 41:18 43:6 filter 25:16,22 51:11 53:5,9,17 54:9 filtering 49:2 final 25:5 finally 70:20 106:23 204:7 finance 102:23 199:7 financing 102:11 find 61:23 138:9 138:24 168:10 finding 59:7 finds 65:11 fine 73:9 75:16 finish 106:20 148:22 176:24 203:2 205:6 finished 83:6 159:9 172:10 firm 155:24 first 11:20 27:18 41:24 57:25 81:14 81:24 84:20 109:16 111:14 118:18 122:15	131:2,2 136:15 171:10 192:18 five 19:16 54:17 62:13 93:25 99:24 183:4 flat 82:19 flexible 51:13 125:4 139:25 149:15 165:24 185:11 flipping 109:18 floor 3:19 6:4,10 6:15 focus 103:4 122:15 focused 55:12,17 56:7,8,11 66:25 67:1 122:1,4 125:18,21 191:11 folks 101:15 102:2 follow 48:25 54:4 64:22 78:9 84:8 104:1 122:12 160:4 following 41:13 51:24,24 52:23 55:10 73:24 80:3 83:11 170:20 food 189:5 footnote 28:9,9,9 28:11,23 48:11 61:20 74:11 110:15,20 118:1 118:17,18 138:7 139:23,24 148:7 156:25 186:13,23 192:18 footnotes 55:23 74:18 foregoing 209:5 212:5	form 43:21 45:9 46:8 49:4 52:7,22 53:13 60:11,16 65:6 66:12 67:14 71:23 74:23 80:1 83:17 84:7 85:15 85:24 86:11,22 88:11 90:2,18 91:24 92:19 98:11 98:22 99:16 115:6 116:1 119:10 120:12 127:20 128:20 130:13 131:22 140:25 141:18 143:21 145:7 157:20 169:25 172:1 174:16 176:16 178:11 181:9,15 182:2 184:19 185:4 186:4,25 187:18 189:20 190:5 191:6 193:8 193:24 194:14 196:3 204:12 format 43:17 former 103:20 forms 186:21 formula 77:19 78:2,4,6,18 79:7 79:18 84:4,12,17 84:22,24 85:8,11 85:21 86:6 87:6 87:15 88:21 89:2 89:7,10 90:1 91:20 92:4,18 93:20 94:10,11,12 94:24 95:1,2,2,8,8 95:12,18 115:24 124:14 126:10,23 127:5 136:18,24	137:17,18 138:3 139:5 146:16,17 147:1,17 148:1,2,2 148:4 156:13 160:5 formulas 75:18 108:6,7 123:16 146:22 formulated 116:23 117:5,18 formulation 99:4 fortune 132:4,5 153:10 forward 173:18 179:7 187:6 found 47:22 50:10 frank 6:3 frankly 39:5 fraud 83:16 free 169:23 173:4 freed 145:22 freeman 2:7 frequency 33:24 frequently 30:4 172:20 friday 1:11 friends 152:5 front 155:10 156:3 198:7 fulbright 4:8 full 15:2 19:22 35:13 57:4 60:10 60:25 61:1 63:8 63:18 65:4 67:11 71:21 72:10,15,16 74:13 77:9,16 79:7,13 129:21 130:4 181:7 192:10,12,15 function 40:16 89:10 177:2
--	--	--	---

[fundamental - growing]

Page 16

fundamental 157:23	146:10 151:11 172:20 185:16	73:1,6 75:17 77:7 81:19 83:3 84:11	goldberg 3:3 11:4 11:5 58:1 195:10
funny 71:17	188:13 190:2	85:7 88:21 89:7	195:18 205:11,20
further 111:13	191:3,18 199:5	95:1,16 106:18	205:22 206:4,8,14
167:25 184:6	geoffrey 6:14	110:21 111:17	207:3
209:9	geoppinger 7:8	116:15 122:8,10	gonna 205:11
g	getting 70:22	127:24 130:22	good 11:4,15
g 44:7,19 45:22	108:14 132:19	136:17 148:1	45:11 53:17,20
47:19 51:8,12	gisleson 3:17	154:9 166:21	68:1 99:22 100:13
52:16 53:4	gist 151:5	168:21 171:4,5,7	154:8,8,21,22
g.1 44:24 47:24	give 11:10 19:24	171:10,12 172:4	155:23 182:21
51:6	32:10 56:10	194:16,25 196:18	183:12,15,20
g.1. 44:20,21 53:4	109:13 156:7	196:21,21,23	189:17 194:13,13
gained 131:18	157:1 198:12	198:24 200:4,21	goods 137:24
gannon 6:8	200:24	201:2,12 202:20	138:18 145:16
gap 150:14 153:13	given 26:10 37:12	203:24 205:8	150:1,2,12 152:10
gateway 6:10	45:18 52:17 90:20	goes 23:22 66:15	175:24 177:12
gcoan 6:14	90:20 93:3,3	90:23 94:21	178:10
geman 2:16	108:25 114:1	111:21 155:3	gordon 6:2
general 42:12	116:21 125:7	going 11:7,17 18:5	gotcha 12:15
119:24 120:7,8	135:9 144:12,25	19:23 20:9 27:25	great 11:23 75:21
127:15 131:13	145:14 166:15	29:9 53:19 54:14	100:1 120:8
137:18 139:5	167:15 202:4	55:6 56:10 65:18	142:19 189:10
142:25 143:8	212:9	65:24 67:24 69:16	greenberg 4:2
144:6,17 145:13	giving 59:16 91:1	70:4 75:25 87:3	183:1
145:13 148:25	91:12 93:8	99:19 100:4,14,17	greg 4:4 182:24
151:5 152:1	glaxosmithkline	109:8,16 111:15	183:13 204:23,23
153:23	8:7 197:10,13,19	113:4 114:2	gross 61:22 103:13
generally 97:4	198:15 199:23	117:20 118:19	137:23 138:8,18
103:1 123:23	202:17 207:21	122:14 133:16	138:21,21
124:7 143:2	glenside 1:12	135:15,17 143:18	group 15:13 33:2
151:13 152:5	go 15:19 26:25	144:18 146:16	66:4 74:2 80:7
generate 22:10	27:6 28:13 29:2,6	154:13 155:3,8,17	117:12 183:13
23:3 25:1 39:15	32:5 34:17 35:25	173:18 174:8	grouping 44:22,25
generated 24:7	36:2 42:3 44:10	175:11 176:2,3	groupings 45:7,16
39:17 65:2	44:18 46:17 47:25	178:5,6 179:3,7	46:4,12,21 51:4,7
generation 64:18	49:6 51:16 53:4	180:14 182:16,23	51:18 52:4
64:19	53:21,23 54:11	183:7,23 187:25	groups 79:25 80:4
generic 82:8,20,21	56:21 58:4,20	188:4,9 197:2,4,6	80:8 106:23
92:23 98:16 99:3	60:18 61:6 62:19	200:19 201:4,14	growing 96:20
116:23 117:5,18	64:21 65:13,24	203:14 205:14	

gtlaw.com 4:3,4	healthcare 3:9,15	64:21 73:17 77:21	174:14,23 175:1,4
guess 120:16	hear 14:9 18:23	80:8 82:3 120:22	175:15,19,25
148:3 192:24	27:3 35:2 59:21	122:12 144:4	178:11 179:8,17
guys 194:20	62:18 100:22	146:19,19 174:14	180:14,20 181:9
h	101:1,3 105:19	176:23 182:22,25	181:15 182:2,7,10
h 6:3 8:1 44:7,19	119:15 131:25	195:23	182:13,17 183:5
47:19 51:8,12	154:24 155:13	holds 144:7,18	184:4,19 185:4
52:16 211:3	169:3 178:21,22	151:11	186:4,25 187:18
h.1 46:16,18 47:24	205:3	honestly 12:16	189:20 191:6
51:6	held 151:25	23:9 126:18	193:8,15,24
h.1. 47:3	155:18 201:16	honik 2:2,3 45:9	194:14,22 195:5
h.2 56:22 64:20,21	help 140:5 182:14	45:20 46:8 49:4	196:3 197:23
64:25 65:2	helpful 28:6 51:2	52:7,22 53:13	201:8,13,18
h.2. 56:17,21	82:14 200:12	54:19 58:15 59:24	202:23 203:14,21
half 14:9	henry 5:3	60:11,16 62:9	205:10,18,21
hand 77:10,19	hereto 212:7	65:6 66:12 67:14	206:2,12,15 208:8
120:23 209:14	hereunto 209:13	67:18 68:15,25	208:10 210:1
handful 103:9	hetero 5:22,22	70:16 71:14,23	honiklaw.com 2:3
handing 94:21	25:12 69:21	72:13,24 74:23	210:2
handled 117:11	154:23,24 155:7,8	76:8,17 79:10	hope 183:17
118:8	155:25,25 156:20	80:1,10,15 83:8,12	hospitals 106:22
handles 118:2	158:20 160:2,12	83:17 84:7,14	117:15 121:13,24
handling 146:14	161:12,13 163:4	85:15,24 86:11,22	hour 26:2,11
hang 204:25 205:1	165:2 167:8,15	87:7,14,18,22	154:2 201:19
happens 30:3	168:5	88:11 90:2,18	202:2 204:3,5,5
happy 33:13 42:3	hetero's 157:4	91:24 92:19 97:6	hours 68:23
73:6 94:25 103:24	163:15 164:7,19	98:11,22 99:16,20	107:22,22 108:1
161:3,23 163:2,6	165:12,12 166:10	99:24 100:7	108:10
178:25 194:16,24	highlight 81:23	112:10 115:6	huahai 3:8,9,15,15
196:18 201:2	highlighted 131:3	116:1 119:10	hudson 2:17
hard 27:3 154:3	hill 3:4 5:17	120:12 122:24	huge 132:8 150:7
head 16:7 75:14	155:24	124:3,18 125:10	huh 63:7 85:6
103:19,25 108:12	hillwallack.com	126:13 127:20	185:21
110:14 111:4	5:18,19,20	128:20,24 130:13	humana 7:6
116:13 164:10	hilton 2:23	131:22 139:2,12	hunchuck 3:18
heading 15:7	hinshaw 6:13	140:9,25 141:18	husch 4:14 168:20
health 5:15 70:19	hinshawlaw.com	143:21 145:7	168:23
111:6,11 112:1	6:14	153:7 154:1,9	huschblackwell....
113:12 139:8	hoc 199:6,11,14	155:2 157:20	4:15
143:17	hold 26:5 32:6,6	159:8 168:2,15	hyman 2:16
	55:20 56:6,18	169:25 172:1	

[hypothetical - instruction]

Page 18

hypothetical 68:7 68:12 69:8,17 70:18 72:2 92:9 92:10,21 140:10 140:12 165:18 189:15 hypothetically 140:4 hypotheticals 188:8	205:23 improper 70:18 140:10 202:10 204:10 impure 163:17 impurity 157:7,19 158:21 incentives 141:15 inceptions 26:16 include 25:3,13 30:17 41:10 43:22 49:23 61:3,9,18 63:21 66:16 85:21 86:21 88:9,17 89:15 91:1 103:6 103:7,11 137:16 138:16 140:7,17 140:23 143:1 178:9 included 17:15 21:15 30:5 36:3 36:22 37:13 39:9 40:24 43:5,5 50:23 57:10,13 66:9 93:20,22 137:17 138:10,12 138:24 139:1 140:2 149:8,21 158:23 166:4,17 166:19 170:24 includes 41:2 106:21 183:14 194:5 including 34:14 40:14 63:12 78:18 86:8 88:4 148:5 175:23 177:11 207:8 inclusion 20:20 47:15 51:15 161:11 162:6	inclusions 140:1 inclusive 61:11 66:17 137:19 138:4 incorrect 189:11 incredible 23:12 incremental 91:14 93:3 incurred 64:8 independent 12:9 70:10 index 10:7 indiana 5:9 indianapolis 5:9 indicate 108:20 indicated 20:23 182:1 202:19 indicator 20:22 individual 23:2 30:14 151:8 173:16 177:8 individuals 85:22 103:16 industries 4:7 industry 12:25 16:20 43:1 46:10 94:19 96:8 101:14 102:5 103:2 118:10,12 119:4 172:8 180:6 181:22 industry's 78:24 information 16:24 24:2 26:7,19,22 30:12,13 33:6,6 34:15 36:24 37:13 38:1,2,11,12 39:25 40:24 42:7 45:17 46:23 48:14 49:20 49:25 93:9 114:15 126:4 134:23	136:8 150:4 157:23 158:11 163:20 167:24 176:18 191:21 192:3,5,15 199:25 200:20 informed 16:25 106:13 informs 107:4 infused 106:24 117:10 ingersoll 4:18 5:2 ingested 190:15 ingredient 99:2 172:11 ingredients 98:20 106:19 injected 106:24 117:10 injury 32:23,25 167:3 173:10 177:17 input 79:7 135:8 inputs 137:2,12 138:15 150:16 inputting 91:15 insist 202:2 insofar 70:17 instance 70:15 instantaneous 172:18 institutional 200:5 institutions 200:9 instructed 193:11 193:14,15,16 instruction 115:13 115:14 125:3 126:15,20 127:14 127:17 149:2,3,16 184:22
i			
i.1 46:16 47:5,10 51:6 i.1. 47:4,5,24 i.2 58:4 62:17 63:4 64:19,24 65:3 i.2. 62:19,20 i.3 62:17 ice 71:16 idea 53:16 118:14 175:22 177:10 178:7 identification 18:11 208:7 identified 17:24 26:20 29:14 95:11 identifier 43:14 illinois 4:5 7:5 ilyse 209:17 imaginable 204:13 imagine 61:15 immediately 172:19 impact 19:18 35:8 35:12 164:3 165:21 implied 45:24 important 103:5 107:1 117:9 120:17 148:13 153:12 155:7			

[instructions - keeps]

Page 19

instructions 9:3 51:25 52:5 124:24 184:25	invoice 108:23 invoices 207:8 involved 107:2 114:1 199:24	185:9 items 150:8 ives 7:2,3	18:5,14 19:13,15 20:1 23:8 24:4,17 24:19 27:5 29:2,4 32:5,8,11 34:4,17 34:19 38:16 40:22 45:5,13,14 46:1,14 52:10 53:1,15 54:13,18 55:2 57:15 59:15,23 60:6,14 62:1,15 64:16 65:7 66:19 66:22 67:22 68:24 69:15,25 70:7 71:16,19 72:3,19 73:3 75:4,15,23 76:4,15,20 77:18 78:1 79:16 80:5 80:11,19 82:1 83:14,24 84:9,15 84:16 85:19 86:5 86:19 87:2,5,9,10 87:21,24 88:16 90:7,22 91:19 92:3 93:16 96:21 97:14 98:3,13 99:9,18 170:14,16
insurance 23:18 30:11,15 40:17 63:11,15 67:2 77:20 79:19,24 80:6,18,24 81:2,5 81:13,18 82:10,16 82:22 97:24 176:17	involves 101:11 involving 104:6 iqvia 50:10 66:15 122:4 160:19 161:10,21,23 166:20 167:10,11 186:17	j	kara 5:7 11:12,16 45:11 68:18 71:15 77:11 80:15 87:19 170:16
insured 22:23 36:25 39:22 77:20 79:18,23 80:6,16 80:23 81:2,5,12,15 81:17 82:5	irbesartan 1:3 issue 22:15 24:11 25:6 26:1 27:8,20 27:22 28:14 29:13 30:1 32:1 37:24 37:24,25 48:4,6,8 48:12,14 50:9,20 52:17 53:24 57:5 57:13 67:4,5,5 71:22 72:11 79:15 84:2 85:23 86:10 86:17,17 104:25 113:10,18,22 114:14 116:7,22 117:4,19 118:9,13 118:23 119:1 121:18,19,23 122:19 123:10 124:12 126:3,19 128:5 129:18 131:7,18 135:24 144:1 146:7 162:10,10,11,14 169:18 172:21 173:22 186:12,16 187:5,9,13,15 188:19 193:5,22 194:4 205:23	jdavis 2:12 jeffrey 7:8 jersey 1:1 2:9 5:21 6:11 jgeoppinger 7:9 john 2:12 3:17 john.gisleson 3:18 joining 45:12 jonathan 4:19 jonathan.janow 4:19 judge 14:4,4,5,15 14:15,19,20 126:15 166:6 june 198:13 jury 61:23 65:11 69:12 124:25 125:2,3 126:15,21 138:8,23 140:1 149:3,7,17,22 150:19 185:1,12 jury's 69:5 justin 7:13 201:9	kara.kapke 5:8 kathy 170:15 katz 2:7 kbi 7:3 keep 19:23 134:6 134:23 136:7 155:3 keeping 135:11,23 207:5 keeps 147:13 150:10
insurer 36:23 39:23 82:9,11	issues 101:12 102:11 132:14	k	
insurers 23:25 97:25		k	
intelligence 43:10		k	
intended 58:11 73:13 74:14		k	
intending 58:11 77:4		k	
interaction 106:4		k	
interest 11:9		k	
interested 209:11		k	
interplay 66:3		k	
interpreted 89:17		k	
interrupt 166:22 174:23,24 203:4,5		k	
interrupted 198:23		k	
introduce 18:5		k	
invade 125:11		k	
invades 112:11		k	
invention 199:8		k	
investigation 157:3		k	

[kept - line]

Page 20

kept 43:15	173:2 180:24	law 124:2,23	134:24,25 136:7
kind 31:8 70:22	188:7 189:21	125:8 155:24	147:4
126:6 127:15	201:3 205:4	184:17	levels 158:15
131:12 152:5	knowledge 41:1	law.com 2:21,22	lewis 3:17
kirstin 7:3	194:8,11	2:23	lhilton 2:23
klinges 3:6	known 114:17,18	laws 46:6	liability 1:3 20:6
knepper 4:14	158:17 188:23	lawsuit 69:21	20:12,17 21:5,10
168:19,20,23	knows 94:19,19	70:10,11	37:12 46:6 47:14
169:5,8,12 170:1,9	147:13	lawyer 46:11,25	48:21 49:9,13
170:12 171:20	kroger 42:4	47:10,13 71:6	50:21,21 58:21,24
172:4,6 174:25	ks 12:13	115:19 123:2	59:1,3,11,18 60:19
175:2,8,11,13,17	kugler's 14:19,20	124:11 139:19	60:21,25 61:25
175:20 176:21	I	lawyerly 204:12	64:15,25 65:17
178:2,4,15,19	I.l.c. 2:20	laying 116:4	66:5,17 67:1,3
179:2,11,12,24	label 51:20 93:8	layne 2:23	69:3 73:25 74:5,8
180:17 181:1,10	99:12	lbresnahan 5:12	74:12,17 84:3
181:20 182:5,9,11	labeled 20:3 30:2	lchb.com 2:17	124:9 126:8
182:16	187:4	leave 205:25	156:14 167:2
knew 158:2 192:4	labeling 103:22	left 33:9 67:12	184:10
know 14:16 16:22	labor 90:25 93:10	68:13 70:15 195:6	liable 115:17
21:4 23:13 24:21	94:20 99:5,7	201:21	license 209:17
33:11 34:22 36:4	laboratories 6:5	legal 7:14 45:10,16	lieff 2:16
39:3,14 41:21,21	labs 5:22 154:23	46:6,24 47:9,12	life 16:15 110:5
42:18 53:3 58:2	155:8,25 160:2,12	58:16 59:25 67:15	146:15
67:25 68:1 73:4	161:13	68:21 69:2 70:14	limit 50:8 201:19
80:25,25 83:7	lack 129:5	83:18 85:25 86:12	202:3 204:3,5,6
92:16 95:24 96:3	ladder 205:9	86:23 119:11	limitations 36:19
98:8,9,12 99:17	laid 115:1 193:12	120:13 122:25	36:21
102:13 106:20	193:17	124:4 126:14	limited 5:22,22 6:6
108:10,16 109:11	language 57:21	139:3,7,14 145:8	14:17,17 37:4
110:5,12 116:18	large 145:18	184:6 210:23	40:10 49:16
117:23 118:23,24	largely 20:20	legitimate 187:10	115:23 124:23
119:2,16 127:15	117:20,22 118:4	187:12,16 190:1	159:3 174:25
131:13 132:6	121:16 122:2,4	190:11	176:14
134:13,14,19	larger 19:14 30:11	legs 206:19	limiting 26:23
146:10 150:7	144:3 147:6	length 31:22	line 9:4,7,10,13
152:15 155:4	176:13	186:14,18	80:21 150:8
157:25 159:15,18	largest 74:25	letters 13:23	159:25 173:19
160:24 161:15,16	late 45:12 154:7	level 26:21 42:23	201:2,2 203:24,24
163:15,23 164:7	laughed 71:18	43:13 74:2 119:6	211:4,7,10,13,16
164:11,17 167:16		124:22 134:16,23	211:19

[list - market]

Page 21

list 29:17,24,25 48:3 84:17 109:23 110:3,8 187:2	logistics 149:12 long 16:4 176:25 look 31:10,12,12 44:20 46:17 55:10 56:14,15 63:17 94:24 118:5 143:18 154:8 162:1,21 168:9 196:19 198:10 202:1,12 204:1	ma'am 35:9 36:5 39:1,14 198:4 madam 100:25 204:25 mail 32:17,25 50:16 169:7 mailed 32:19,20 32:20,22 33:1 50:18 main 110:21 maintain 102:16 135:3 maintained 134:4 major 132:4 143:11 majority 116:23 117:6,23 making 71:14 82:13,13 99:13 154:25 158:3,5,7 management 54:10 151:15 manager 169:7 179:14,23 180:12 manager's 179:16 manner 151:14 203:13 manufacture 132:25 manufactured 128:6 158:20 manufacturer 23:19 25:7,10,20 26:21 28:25 29:13 29:17 35:15 40:13 51:18 52:4 56:9 58:22 59:7 60:9 66:4,10,18 67:3,6 89:5 92:13 105:10 114:7 123:7 134:24 142:6	150:21,21 151:1 151:11,13 152:14 153:5,5 157:24 158:16 159:18 165:12 188:24 192:5 manufacturers 28:22 29:24 30:3 37:25 48:16 57:13 58:10 64:5 67:8 68:7,10 70:11 73:13 74:1,6,13 103:4,12 105:21 113:23 114:2,17 119:6 120:22 121:2 133:18 134:12 135:4 136:3,9 142:8 151:17,23 152:8 152:17,22 167:1 184:1 188:13 189:4 manufacturing 106:20 194:13 marginal 90:24 91:3,3 mark 18:6 33:18 202:3 marked 9:12 18:10 70:13 202:6 204:16,21,24 208:6 market 2:4 30:4 74:21 75:3 102:21 114:1 118:3 119:8 120:11 123:9 135:18 142:7 143:12,12 144:4,8 144:19 151:7 157:24 158:13
listed 16:22 17:23 18:17,21 19:5,5 21:15 25:25 29:11 29:16 41:25 44:6 48:21 54:1 59:10 59:12 70:11,12 74:25 90:9 110:10 115:2 117:21 139:5 163:5 166:20 listing 15:9 lists 32:2 literally 26:2,11 78:23 literature 175:21 178:7 179:6 litigation 1:3 14:21 18:3 140:7 146:3,8 little 19:14 34:15 101:2 108:13 111:13 120:25 123:12 151:17 185:5 199:3 live 38:4 192:14 livenote 1:15 liza 6:9 llc 2:2 3:9,15 4:21 5:5 llp 2:11,16 3:2,10 3:17 4:2,8 5:7,11 5:17 6:2,7,13,18 7:2,8 located 32:13 50:16 location 32:25 logistically 25:16	looked 12:5 103:10,13 104:19 107:21 looking 30:21 56:13 78:6 79:18 80:20 87:6 89:23 94:13 105:12,15 105:17 106:12 168:11 looks 132:11 143:8 losartan 1:2 210:4 211:1 212:1 lost 77:12 lot 13:14 30:12 39:14 101:8 102:4 105:18 108:8 118:24 129:3 132:19 133:18 194:3 lots 68:21,22 152:4 loud 27:2 louis 4:16 louisiana 2:24 love 140:12 188:8 low 82:8 101:3 luke 5:12 lwalsh 6:9		
	m		
	m 1:11 2:5,7 4:3 4:10 5:7 6:9,14 10:2 209:6		

[marking - mischaracterizing]

Page 22

marking 20:2	mazieslater.com 2:8	measures 184:3	139:24 148:24
mash 87:18		mechanical 86:15	149:15 151:6
mashing 87:19	mckesson 4:12	87:16 89:21 90:14	185:11 186:3
massachusetts 6:15	111:6,11 112:1	122:1 124:11	methodology 70:25 122:17
massive 42:21	113:12	126:19	156:13 162:7
144:2	mdl 1:2	mechanically 65:8	171:8
master 14:3,14	mean 24:18 30:24	88:14 116:3	microphone 101:5
match 50:19	31:1 32:19 34:5	125:16,25 148:23	million 69:23
147:24	36:4,20 37:1	mechanism 203:19	118:7 135:16
matched 48:17	40:25 41:4,22	media 11:2 54:21	160:13 161:7
material 190:8	42:18 45:8 55:20	54:25 100:4,10	162:4
materially 143:5	58:23 65:8 66:1,2	154:13,18	millions 23:13
materials 11:24	67:10 71:6 72:16	medical 106:23	172:15
18:8 20:3,8	73:6,15 74:15	199:16	mine 69:9
127:11	78:20,22 81:1,3	medication 171:24	minus 48:6 61:11
mathematical 68:22	86:14 87:7 90:9	172:10,23	65:20,20 84:18
matt.knepper 4:15	94:25 102:25	medicine's 199:8	94:10 95:9 126:25
matter 8:7 16:17	106:16 109:1	199:15	127:19 129:24
17:4,12,15 86:23	113:16 114:4	meet 13:23 154:7	130:6 173:23
103:24 104:19	117:6 119:13,23	meetings 102:10	177:2,4
109:24 116:6	120:16,16 125:21	megan 7:4	minute 26:2,11
117:20 119:24	125:24 132:4	members 85:22	148:21,22 156:9
120:7,8 122:1	134:10 135:10	86:10 104:18	195:6
126:2 128:4	136:12 141:2,11	114:18 135:2	minutes 54:17
130:11 131:13	143:10 145:1	136:5 142:13	99:24 123:17
132:14,17 141:23	148:6 150:6,24	membership 86:23	183:4,22 204:2
142:25 143:19	152:12,13 164:22	mentioned 14:18	misbranded 27:24
144:7 145:10	164:22 165:4,11	25:9 28:11 51:19	48:10 186:2,10
146:4 152:3	165:14 166:22	63:20 93:5 99:10	188:14 189:8
153:23 175:1	170:18 171:7	102:22 104:4	190:2,7 191:3,18
199:21 204:3	182:5 183:21	107:16 133:24	193:5,23 194:10
matters 65:16	194:15 196:4,18	147:16 148:10,19	misbranding 186:20 192:7,20
133:15 177:19	200:14	149:10 152:19	mischaracterizat... 171:3
matthew 4:14	means 34:13 46:4	198:22	mischaracterizes 193:9
110:9,12 168:20	93:15 182:18	merely 204:1	mischaracterizing 143:24 202:24
maz 7:4	196:6	meridian 5:8	205:18
mazie 2:7	meant 80:17	met 190:8	
	119:16	method 51:13	
	measure 123:25	78:23 125:4 139:4	
	127:12 128:3,10		
	184:17		

[misconduct - note]

Page 23

misconduct 27:11 27:13,14 mismatch 57:21 missing 31:15,16 missouri 4:16 misspoke 80:16 111:15 mistakenly 43:22 mistakes 53:23 mix 121:1 model 181:3 molecule 116:22 117:5 moment 163:18 172:2 173:1,8,9 191:8 momentarily 11:6 moments 160:5 monday 13:2 money 72:11 89:4 127:8 130:16 176:11 178:9 monroe 7:5 month 22:15 23:20 25:3,5,10,19 25:21 26:19 40:14 161:22 184:14 186:15 months 107:18 108:16 morgan 3:17 morganlewis.com 3:18,19 moring 5:11 morning 11:4,15 11:24 45:11 68:4 100:13 102:23,24 170:17 morris 3:2,10 mortar 32:15	moskowitz 1:14 209:3,17 motion 168:8 move 44:2 54:14 131:13,15 173:18 178:15 179:7,8 190:25 204:14,16 moved 129:18,22 150:13 173:16 movement 129:20 moving 123:13 127:9 130:17 132:13 172:15 mulberry 6:10 multiple 31:23,23 39:5 62:9,12,13 64:2,3,4,5 74:12 83:21 101:16 147:7,7 198:13 200:14 201:21 204:8 multiplied 136:25 162:3 multiply 137:13 137:16 murtha 5:17 mute 11:13 194:21 mylan 6:5,6 69:22 103:11 118:18	name's 183:12 named 17:15 106:6 179:6 names 24:10 105:5 105:10 national 40:5 199:7,14 native 43:17 44:12 161:21 163:4 nature 163:17 ndc 22:17 24:10 25:7,20 26:20,20 29:14,21,24 30:5 34:21 35:5 40:14 50:10 51:18,21 52:4 54:5 57:13 59:7 118:22,24 119:6 133:19 134:24 186:15,24 187:2,3 ndcs 25:12 30:1 160:10 necessarily 165:11 167:2 necessary 212:6 necessity 66:7 need 21:3 51:2,7 52:14,15,18 54:6 79:3 88:1 110:23 154:4 159:6 173:2 207:2 needed 135:8 needs 68:9 194:20 negotiate 152:8 negotiated 98:10 167:9 neither 209:9 net 127:10 137:23 138:22 network 179:16 180:8	never 34:7 54:7 104:13,16 152:6 new 1:1 2:9,18,18 2:24 5:21 6:11,20 6:20 51:11 52:16 52:17 53:6 199:17 200:20 newark 6:11 news 183:15 202:8 nice 183:21 night 11:24 102:24 nitrosamine 157:6 157:19 166:12 nitrosamines 157:13 noise 27:2 105:19 132:19 155:13,15 nominal 98:18 non 42:11 43:6 149:18 188:23 190:2,2 191:3,3,18 191:18 192:7,7 normal 31:8 102:3 110:5 normally 107:12 norris 4:9 north 5:4 norton 4:8 nortonrosefulbri... 4:9,10 notary 209:4 212:13,19 note 47:6 58:15 59:13,24 68:15,16 69:25 70:16 76:8 112:10,10 122:24 124:3 125:10 126:13 139:2,12 140:9 154:2 168:3 174:7 183:23 184:4 210:10
	n n 2:1 3:1,18 4:1 5:1 6:1 7:1 name 11:15 19:17 25:6,7,11 30:17 34:20,21 35:5 39:19 40:4,13,13 100:14 133:18 154:23 155:23 178:6 185:25 186:9 187:10,16 198:3		

[noted - ones]

Page 24

noted 46:18 124:19 212:7 notes 45:21 63:17 209:8 notice 207:14 number 8:2 11:2 17:25 39:21 40:6 54:21,25 68:17,23 68:25 69:23 70:2 70:2 100:4,10 103:20 108:10 109:2 118:2,24 154:13,18 160:16 160:17,24 161:5,7 161:16,17 187:3 201:19,19 206:20 206:21 numbers 18:3 35:23 53:6 65:2 72:22 141:15 162:23 numerous 184:9 192:22 nw 3:13 5:14	131:22 140:25 141:18 143:21 145:7 157:20 169:25 172:1 174:14,16 178:11 181:9,15 182:2 184:6,19 185:4 186:4,25 187:18 189:20 191:6 193:8,24 194:14 196:3 202:5,12 203:16 204:13 objecting 38:12 objection 38:9 39:11 58:15 59:24 68:16 69:1 70:16 70:21 72:13,24 76:8,11,17 79:10 97:6 112:11,13 122:24 124:3,18 125:10 126:13 139:2,12 140:9 153:7 175:25 179:17 180:17 184:4 objections 125:14 obtained 91:23 169:23 obviously 113:25 200:9 occupy 119:25 occurred 33:20,24 33:24 61:19 69:20 69:20 70:9 143:9 165:20 173:10 occurrence 33:12 occurs 32:23 143:8 167:4 177:18 offer 71:14 84:21	offered 84:4,5 181:24 204:7 offering 115:3,16 office 199:5 offline 168:13 offset 50:4,6 65:22 138:8 148:11 166:18 171:18 offsets 61:3,18,22 63:14 130:2 137:24 148:8 149:4,21 150:18 167:3 oh 35:10 71:17 72:8 83:10 110:15 ohio 7:10 okay 12:15,15 13:3 14:7,12,24 15:4,13,16,20 17:16 19:19,23,23 22:6,22 24:13 26:4,13 27:6 29:2 29:12,18 32:9,10 34:25 35:7,25 36:6 39:7 42:17 42:20 44:10,18,24 44:24 46:15 47:1 47:17 49:5 54:14 55:6 56:12,20,22 57:3,9 60:18 62:16,20,20 64:24 64:25 66:1 69:16 72:8 73:5 75:17 75:21,23 76:21 77:2 78:8,10,21 79:3,17 81:8 82:2 83:3,10,13 84:10 84:11 85:7,10,20 87:2,14,21,25 88:8 88:21 90:8,13 92:8,20 94:13	95:4 97:3 99:24 100:13,21,22,24 101:1,4,20 104:1 104:10 107:21 108:4 109:5,15 110:8 113:6,7 116:19 118:13 119:1,23 120:6 122:13 123:1,16 129:2 130:20,23 131:5,19 133:9 136:17,21 137:15 140:11 142:6,16 142:19,20 148:1 150:16,23 151:5 152:18 153:21 155:6 156:5,10,11 156:12,19,24 158:19 161:25 164:7,11 165:1,6 166:7,23 167:23 170:22 171:21 172:4,7 173:18 178:15 182:17 183:5,24 184:16 184:25 185:25 186:8,19 187:25 188:14,20 189:14 189:24 190:25,25 191:14 192:13,16 192:24 194:23 198:5,9,13,22 200:7 205:6,8 206:8,9 old 206:12 once 53:12 59:4 ones 17:15 25:25 42:1 43:20 69:11 103:23 117:19 163:24,24,25 172:21
o			
o'clock 154:2 o'reilly 6:7 oath 11:21 object 45:9 46:8 49:4 52:7,22 53:13 60:11,16 65:6 66:12 67:14 71:23 74:23 80:1 83:17 84:7 85:15 85:24 86:11,22 88:11 90:2,11,18 91:24 92:19 98:11 98:22 99:16 115:6 116:1 119:10 120:12 127:20 128:20 130:13			

[ongoing - particular]

Page 25

ongoing 69:1 opaque 107:11 open 31:19 207:5 opened 31:22 operate 142:7 operating 102:20 opinion 14:24 38:20 45:6 46:11 46:21,24 47:9,12 47:14 59:16,25 70:20 84:5 122:25 124:4 129:6 138:25 139:8 187:11 189:25 191:7 194:12 opinions 11:18 14:2,13,19,20 16:16 17:7 46:5 100:15,19 106:13 114:23 115:3,16 115:22 opportunity 11:10 33:14 201:25 202:4,11 opposed 57:22 optum 42:4 optumrx 6:21 oral 97:19 98:16 orally 116:23 117:5,18 orals 118:4 oranges 59:8 order 32:17,25 50:16 51:21 70:4 98:17 132:7 169:7 181:2 organization 102:12 organizations 117:12	original 53:21 54:11 196:1,4 orleans 2:24 ostfeld 4:4 10:6 182:18,20,24,24 183:1,11,13 184:15,24 185:14 185:20,24 186:7 187:7,24 189:23 191:13 193:19 194:7,20 195:1,7,9 196:7 198:2 200:6 202:13 203:1,21 204:20,25 206:21 207:4,16,17 208:9 ostfeldg 4:4 outcome 209:11 outlined 27:17 162:7 outpatient 117:15 121:24 output 8:3 18:7,17 18:18 20:4 21:25 24:7 26:16 29:3 29:19 33:4 44:5,8 51:10 52:11,16,21 53:5,12 outside 60:5 67:21 69:13 70:14 71:2 71:12 92:11,11 140:6 overhead 149:19 overlap 200:10 owed 65:15 oxford 3:19 6:4	packages 147:5 packs 147:7 page 8:2 9:1,4,7,10 9:13 10:4,5,6,7 28:4 45:23 46:18 50:3 57:16 73:22 82:4 89:7 109:2 109:17 111:14,16 111:17,18,21 130:22 146:17 148:4 156:8 159:23 169:13 171:5,10 198:10 198:13,24 211:4,7 211:10,13,16,19 pages 15:6 108:6,9 108:11 109:18 111:22 paid 23:19 30:10 35:13,21 39:24 40:16 49:16,21 50:12 57:4 60:10 60:21 61:1,10,11 63:8,19 64:1,10 65:4,18,19 67:8 68:10 69:22 78:13 78:19 79:14 82:23 82:25 84:3 86:16 86:21 88:10 97:18 105:8 128:4 129:23,24 137:23 137:23 138:19 143:2 159:16 160:21 161:10 162:9 167:4,12 174:5 176:16 181:13 painfully 178:12 pale 204:11 panels 102:9 103:17	paper 28:7 91:10 118:6,6 papers 16:6,21 105:14 paragraph 15:2 27:7,24 28:1,10 32:4,7,9 49:6,8,11 55:16,19,24 61:7 73:7,7,21,21,23 75:18 77:8,23 78:3,3,7,9 83:3,5 84:12 112:22 113:8,14 116:15 116:21 118:1,18 122:8 127:1,25 128:2,7,17 130:22 130:23 132:24 136:19 138:14 156:6 160:6 171:6 171:11,12,14 172:5,8 173:20,21 192:18 199:1,1,2,3 202:20,20 paragraphs 27:18 28:18 48:1,23 83:23 115:2 parkway 2:8 part 13:1 27:14 31:17 45:17 79:17 81:14 102:6,6 103:1 107:9 120:17 126:6 136:18 137:16,25 137:25 138:22 145:23 147:14 148:4 179:15 180:8 199:2 particular 17:4 26:9 33:3,3 35:14 59:19,23 60:8,8 64:9 65:22 114:11
	<p>p</p> <p>p 2:1,1 3:1,1 4:1,1 5:1,1 6:1,1 7:1,1 p.m. 154:5,12,16 154:16 201:15 208:13</p>		

[particular - pharmacy]

Page 26

139:10 140:6 141:13 151:19 152:10 156:15 particularly 82:7 parts 108:20 196:8 196:12,19 201:23 party 22:21 49:17 61:2,11 65:14 97:11 157:10 158:1 159:14 160:22 163:22 164:19 165:16 167:9,13,17 176:12 181:24 191:25 192:4,9 209:10 pass 11:7 99:19 patient 35:13 41:4 57:4 60:10 63:8 63:18 65:4 90:21 91:1,4,13 93:3,11 94:22 174:6 177:8 181:4 patients 36:25 78:18 119:22 121:9,20,25 166:18 pause 176:25 pay 30:15 63:22 67:13 68:7,14 70:11 78:12 79:18 79:23 80:6,7,17,22 80:23 81:2,5,13,13 82:6,9,11,15 88:20 89:4 91:22 97:20 97:25 171:24 paying 77:10,18 78:11,22 79:1,1,6 79:9,19,24 80:24 81:10,17,18,20,25 134:12	payment 22:20 23:18 40:17 63:16 67:2 71:7,9,10 78:23 81:18 82:10 88:15 166:18 payments 23:24 36:23 63:11,12,13 67:4 77:9,17 78:25 82:19 96:7 164:11,17 165:2 165:11 176:10,15 176:17 177:3 payor 22:21 49:17 61:2,11 78:5 160:1,12 161:7,22 163:12 164:4 181:24 192:10 payors 65:14 97:11 157:10 158:2 159:14 160:20,22 161:10 162:11,15 163:22 165:16 166:1 167:9,17 176:12 192:1,4 pays 30:11 77:19 97:15 pbm 41:2,3,7 180:7 pbms 40:24 pc 4:18 5:2 pending 203:12,17 pennsylvania 1:12 2:4 3:7,20 5:14 6:4 penny 134:7 people 79:1 81:10 81:12,17,17 82:5 percent 82:25 118:2	percentage 74:21 75:6,11 82:22 114:11 117:24 118:15 119:2 perfect 77:2 period 25:1 26:9 26:11,23 27:10,13 27:20 28:16,22 31:24 35:18 57:5 57:8,14 64:9 80:23 84:24 85:4 85:14 86:17 88:24 89:11,13 95:15,20 95:22 114:2,14 116:7 143:4 144:12 145:15 156:16,17 160:9 160:19 162:10 164:5 187:9 188:17,18 periods 24:11 25:23 28:18,20 37:25 48:13,15 64:6 67:5 96:19 permitted 175:4 180:22 206:17 person 41:5 personal 194:8,11 perspective 60:24 64:10,18 65:2 78:25 88:1 89:3 89:22,24 90:15 158:8,10 159:11 159:14 163:20,22 177:6,21,23 190:6 pertains 168:5 ph.d 8:5 207:19 210:5 211:2,24 212:2,4,12 ph.d. 1:11 2:5 10:2 209:6	pharma 3:21 pharmaceutical 3:8,8,14,15 12:25 16:20 43:1 46:10 96:8 103:2,4 118:3 151:8 pharmaceuticals 4:6 6:6,12,16 pharmacies 16:23 17:14 23:11,17,23 25:18,24 26:8 32:24 36:13 37:1 37:21 38:1 39:15 40:10 41:11,12,19 41:20,22,23 42:8 42:11 43:6,8,19 50:5 51:17 74:25 103:14 106:22 114:8 116:24 117:7,16 119:24 120:25 121:6,8,14 121:14,20 131:7 142:12,20 146:6 152:23 169:22,22 170:7,10 171:18 171:24 172:12 173:8 174:19 176:6 pharmacist 91:15 93:10 pharmacy 7:6 11:18 13:7,11,21 13:25 15:10 18:2 27:15 29:10 32:13 32:17 36:11 37:17 37:19 38:23 39:10 41:7 43:2,13,13,13 43:18,22,23 44:6 49:15,22 50:8,15 50:16,17 59:19 63:22 66:8 67:12
--	--	--	---

[pharmacy - pretty]

Page 27

68:13 74:21,22 79:14 83:16 89:4 91:12,17,22 92:12 94:22 97:18 98:4 98:9 99:14 142:23 144:14,15,15 153:5,6 158:22 166:19 167:13 168:25 169:6,7,8 169:18 170:25 172:9 175:23 177:11,12 178:9 178:10 179:14,15 179:15,23 180:4 180:11 181:12,25 pharmacy's 175:24 phase 149:1 philadelphia 2:4 3:7 phrase 27:12 81:14 physical 32:14 78:14 physician 40:4 physicians 121:13 pick 62:16 142:21 201:6 picked 30:5 51:18 51:19 56:25 187:2 piece 175:21 178:6 179:5 pietragallo 6:2 pietragallo.com 6:3 piling 202:7 pill 147:7 pills 147:6 160:11 163:17 pittsburgh 3:20 6:4	pizzi 6:7 place 127:10 129:19,22 130:17 150:13 162:21 209:7 plaintiff 59:17 128:5 plaintiffs 2:10,14 2:19,25 27:8 36:9 36:16,18 37:8,15 38:22 39:7 45:1 45:18 51:5 100:7 113:9 122:16 188:3 plans 96:25 play 129:17 players 143:11 plaza 4:15 please 19:22 20:10 44:24 45:22 54:16 57:24,24 59:22 60:15 66:23 75:22 86:4 94:24 99:23 109:9 111:17 112:24 115:11 116:14,17 119:18 122:8,11 128:1 156:6 159:20 161:4 163:10 175:9 176:23,24 183:4 203:2,2 205:1 pleasure 101:15 102:18 plus 25:10 192:4 pocket 40:16 78:22 79:1 84:22 85:12,20 86:7,18 86:20 87:13 88:3 point 11:7 32:15 32:23 48:5 60:22	61:3,17 63:24 91:4,7 92:1 93:4 93:13 94:15 96:11 96:23 97:13,20 132:13,14 155:7 159:2,11 166:16 167:4,5 173:10,11 174:21 177:9,13 177:18,19 182:4 197:21 207:16 pointing 22:7 points 168:10 portion 15:1,3 30:15 portions 108:24 197:16 202:15 position 68:12 204:4 possession 203:9 possibility 165:24 possibly 141:5 176:4 203:23 post 182:4 potential 157:13 potentially 50:1 61:15 149:14 207:7 power 143:12 144:4,8,19 151:12 powerpoint 206:23 ppu 85:11 ppudt 136:25 137:12 practice 54:11 88:6 practices 53:20 194:13 pre 182:3 preceding 48:22	precise 189:17 precisely 94:5 prefer 28:7,7 premise 129:11 prepared 196:1 197:8 204:8 preparing 12:21 188:2 prescriber 40:5 prescribing 40:4 prescription 21:19 21:23 22:2 23:22 28:21 29:20 30:6 30:8,16 32:18,20 32:24 33:1 35:14 37:6 39:16,22 40:1,20 41:6,18 43:6 50:18 64:12 65:21 75:2 81:11 82:7,21,21,24 84:2 89:18 90:20 94:21 97:12 106:18 118:7 157:17 172:14 173:16 177:7 180:10 prescriptions 16:25 22:23 23:1 23:25 37:3,18,22 39:9 41:11 42:8 135:17 156:21 160:21 172:16 present 7:12 55:16 70:24 73:24 74:4 74:6,9 174:8 presented 184:13 185:8 preserve 69:1 preserved 133:20 205:24 pretty 143:13 153:11 196:20
---	--	---	--

[prevent - provide]

Page 28

prevent 74:6 175:7 204:15	137:21 145:3,11 199:1,1 200:2,10	157:11,12 158:17 160:18 161:22	138:7,8 148:8 173:25 177:20
previous 49:19 73:22 81:15 183:18	problem 87:19 155:4	164:19 166:1 167:10 174:20 184:14 192:8 199:17	188:21 profited 48:3 129:20 131:6,10 173:21
previously 70:17 71:24 72:14 124:19 197:8	procedure 49:7 50:24	production 9:6 190:8	profits 48:5 61:8 61:21 126:25 129:12 135:9 139:9 140:5,8 141:2,4 169:17,22 173:23 175:23 176:7 177:2,11 178:8
price 27:10 79:8 84:1,2 129:23 130:4 133:13,16 134:11,14 136:10 136:11,13 138:18 156:16 160:7,8 161:6,9,19,21 162:3,22 163:1,4 163:11 167:12	process 31:17 65:13	products 1:3 22:15 24:12 27:9 27:22 28:14 48:4 48:8,12 50:5 61:16 96:18 99:11 113:10,18 114:16 116:22 117:4,11 118:14 119:2,8,21 121:11,18,19,23 122:19 123:3,14 128:5 129:11,14 129:18,21 130:5 130:11,17 131:7 132:25 133:1,13 133:17 136:4 137:22 138:20,20 142:9 145:3,14,18 145:20 146:7,13 147:8 152:14 157:14 158:1,12 159:15 160:9 161:12 163:23 165:17 167:5,14 173:7 176:7 186:12 187:5,12 187:15 190:6,12 190:14 194:4,6	programs 24:21 proof 123:21 proper 123:25 127:12,18 128:9 propose 126:23 proposed 108:7 124:14 139:25 148:25 proposing 115:24 prospective 157:9 158:8 159:13 190:5,18 prospectively 143:4 153:1,3 163:21 164:1 167:18 192:11 protection 46:19 56:15,24 58:12 protective 70:4 provide 30:13,13 30:20 31:14 84:19 161:3,5,23 163:2,7 163:10 167:25 177:15 200:19 203:18 204:21 208:2
prices 137:20,20 137:23,23 138:22 138:22 145:14 162:9,17 167:9	procurement 93:19,22	produced 18:2 37:16 57:6 111:6 112:19 146:3 151:24 170:6 176:15 201:21 207:8,10	
primarily 11:17 16:19	procuring 175:24 178:10	producing 110:17 110:19	
princeton 5:21	product 19:17 22:16,16 23:19 25:6,7,11,20 26:20 26:20,24 27:9,20 34:20,21 35:5 38:12 40:13 48:7 48:16 50:9,13 64:8 79:8 80:22 84:23 85:3,3,13 88:2,24 89:6,11,12 92:7 95:14,19,21 99:3,4 105:23,24 112:12 120:11 125:11 129:4,5,8 135:25 136:7,8 149:18 151:18,20 152:11 156:16,17		
principles 153:13			
princeton 3:8,14			
printing 93:8			
prior 87:4 116:9			
private 51:20 99:12 103:21 187:4			
privately 30:2			
privilege 125:12 206:25			
privileged 38:11 38:19 76:10			
privileges 112:12 125:12			
probably 34:16 49:5 52:14 121:21 121:22 123:17		professor 101:9 104:6 profile 93:13 profit 61:22 63:25 92:17 98:19 123:12 132:9	

[provided - really]

Page 29

provided 17:12 18:8,19 19:4,8 20:3 22:14 23:16 24:3,9 25:18,21 26:7,9 29:23 31:10,12,13,14 33:7 36:11,21,24 37:3,14,21 38:1,3 38:5 40:7,10,18 41:10 42:1,24 43:11,12,16,20 44:1 45:1,24 46:3 46:12,19,23 47:6 47:15 48:14 49:20 49:23 50:2,11 51:16,25 52:19 63:15 65:11 74:2 89:19 96:5 168:6 170:25 176:9,18 177:3,5,24 186:23 187:1 200:1 providing 162:25 163:1 167:12 proving 38:20 public 12:22 16:7 42:21,22 102:20 102:23 118:19 132:8 153:14 207:22 208:4 209:4 212:19 publicly 132:8 published 104:13 104:16 pull 109:7 198:8 pulled 101:4 purchase 79:8 123:7 133:16 151:16 172:10 173:3 purchased 80:22 133:13 135:3	138:20 172:25 purchaser 79:9 purchasers 79:19 79:19,24 80:7,24 81:21,25 131:15 131:16 purchases 77:10 77:18 78:11 79:7 92:12 116:24 117:6 158:7 purchasing 117:12 134:13 142:9 145:17 173:7 174:12 purely 89:24 90:15 purity 190:9 192:6 purposes 14:21 16:16 43:10 70:3 70:4 86:6 89:25 99:18 115:20 130:14,15 157:16 166:4 186:10 188:7,12 purview 69:13 71:2 put 181:5 200:12 200:17 203:8 putting 64:17 65:1 93:6,7 120:10 207:17 208:1	89:10 94:16 95:19 145:18 147:3,4 156:15 160:7,8,11 160:25 161:20 162:2,22 163:2,4 163:11,15 question 11:20 21:21 22:7,8,25 26:13,14,18 28:17 33:18,21 35:3 36:8,14 39:2,4,6 39:14 41:9,14 42:13 46:20,23 47:12 52:24 58:2 59:21 66:20,23 67:24 68:18,19 69:2,17 70:5 72:1 72:7,21 73:5,10 75:11 76:23 78:10 78:15 79:22 84:8 86:3 87:3 90:13 93:24 95:7 97:2 107:24 110:24 119:17 120:4 129:7 131:23 139:13,17 140:20 141:1,20 159:7 161:19 166:13 169:5 174:3 175:3 175:10,16,18 178:16,17,20,24 178:25 179:1,9 180:3,23 181:8,19 182:6,12,14 187:23 188:16 191:15 195:2,14 195:16,19 196:22 197:3,6,7 198:1 202:11,14 203:11 203:17,20,24 204:9	questioned 170:16 questioning 11:8,9 173:19 questions 9:12 11:11,17 77:3 87:4 100:15,17 140:13 152:4 155:9 156:1 161:25 167:25 188:7,12 189:22 206:17 quick 127:25 quite 30:4 187:22
			r
			r 2:1,12 3:1 4:1 5:1 6:1 7:1 209:1 211:3,3 rachel 2:16 ramifications 46:7 random 56:25 range 96:13,15,16 raspanti 6:2 reach 106:22 read 14:19,20,22 14:24,25 15:2,3 32:10 38:23 51:3 83:4,9 110:23 175:9 210:9 212:5 reading 19:17 ready 13:2 100:8 172:19 real 127:24 reallocation 70:22 really 22:17 69:2 70:22 77:4 82:8 82:24 98:18 108:22 117:19 118:23 122:14 125:17 129:17 130:4 143:11 145:9 146:10

[really - repackaged]

Page 30

149:1 166:13 204:17 realm 70:14 reason 210:11 211:6,9,12,15,18 211:21 reasonable 61:23 138:9 reasons 71:24 rebate 141:8,9,14 141:17 142:24 166:24 rebates 61:4 138:16,19 139:11 140:7,18,24 141:6 143:1,18 144:25 145:4,19 148:15 148:18 166:8 167:2,4 rebazan 3:11 rebecca 3:11 reboot 132:3 recall 25:3,5 29:17 29:25 33:11 56:5 116:12 164:3,20 194:6 recalled 27:22 48:9 163:16,23 165:16,25 recast 51:20 receipt 210:18 receive 180:23 received 123:8 136:14 176:10,11 205:16 receiving 167:24 181:25 record 11:3 18:9 19:11 54:22 55:1 70:1 75:25 76:3 100:5,11 154:9,14	154:19 155:17,19 155:21 168:3,16 180:16 183:7,10 201:12,13,15,17 202:14 203:3,8 205:9,19,24 206:1 206:3,9 207:13,18 recorded 160:18 161:10,21 records 108:18 131:20 203:7 redo 53:19 reduce 132:20 refer 15:13 18:12 18:16 95:9 109:8 112:21 116:20 197:14 201:4 reference 27:17 28:13,14 55:20,21 63:18 77:8 78:11 203:10 206:23 referenced 18:1 28:1 77:23 172:23 173:20 192:18 210:6 references 12:9 referencing 59:13 referred 22:19 55:24 58:19 113:13 referring 15:17,18 27:14 59:11 78:12 78:13 85:4 89:2 90:5,12 128:9 134:8 138:15 182:3 refers 28:11 128:17 reflect 60:7 168:16 169:21 199:19 206:9	reflected 37:18 57:6 169:16 174:5 reflection 45:16 46:5 reflects 41:18 refund 71:21 72:10,15,16 refunds 165:15,25 regarding 12:5 46:6 55:7 67:16 100:19 113:5 135:23 192:6 registered 37:5 regular 31:4 regulation 102:12 200:5 regulator 192:4 regulators 43:15 reimbursed 181:13 reimbursement 102:11 181:23 relabeled 30:2 51:21 99:11,15 relabeling 105:22 relate 28:20 96:17 99:2,3 related 20:20 21:14 40:12 60:21 61:17 65:18 67:4 78:4 94:20 95:2 98:25 102:11 103:21,23 104:25 105:21 106:3 118:4,4 124:8,9 129:22 130:7 146:7 148:12 149:18,25 150:1 167:6 187:4,11,12 191:10 209:10	relates 1:4 22:25 84:3 96:2 relating 14:3,14 15:9 16:15 relative 93:12 151:7 release 154:10 relevant 24:25 26:23 27:10 28:18 28:21,22 35:18 47:22 48:15,16,16 48:18 50:1 57:5 57:14 59:6 61:24 61:25 148:17 160:9,19 173:12 176:20 relied 17:11 24:10 127:14 192:17 193:21 rely 16:14 17:8,10 24:8 49:14 127:11 remainder 47:19 47:20 82:11 remember 12:16 51:19 84:12 103:15 104:8 105:3 107:19 108:4 142:7 171:1 remind 70:23 remiss 108:13 remove 89:20 removed 61:22 138:8 170:5,6,22 171:16,22 rena 1:11 2:5 8:5 10:2 207:19 209:6 210:5 211:2,24 212:2,4,12 rendering 114:23 repackaged 30:2 99:11,14 187:4
---	--	--	---

[repackager - retailer]

Page 31

repackager 51:19 164:8,12,18 165:13 repeat 115:11 140:20 164:14,14 192:25 replicated 201:24 report 8:5 12:3,8 12:10,17 15:5 20:19 25:2 27:7 27:18 28:12,13 32:3 33:15 44:7 47:25 48:22 51:3 51:25 52:5 54:1 55:8,12 60:5 61:7 62:8 72:17 75:18 77:7 83:4 88:22 93:21 94:2 103:3 107:17,18,23 108:2,6,19,20,25 109:7 110:21 112:21,22 115:21 116:15 117:23 118:21 127:25 132:10 155:10 156:2,25 157:22 159:21 160:6 161:1 162:7,21 163:1 166:20 169:14 170:3 171:6,23 173:6 174:13 181:6 184:13 185:8 192:19 193:12,17 196:10,14,16,24 197:9,17,17 198:25,25 200:4 200:12 201:3,9,25 202:16,21 203:9 203:14 204:20,23 206:22 207:19	reported 43:15 133:17 reporter 1:15,15 11:12 14:5,7 16:1 16:9 17:18 23:6 24:16 34:1 45:2 57:11 59:20 64:4 66:21 67:17,19 71:8 75:8 77:11 77:15 80:13 81:23 91:5,8 96:14 97:22 100:16 101:1,2,17,20 104:15 105:7,13 107:10 110:18 112:17 113:20 114:19 115:10 120:19 121:4 125:1 128:12,23 129:12,15 130:1 131:24 132:15 135:13 138:11 140:19 141:25 153:16,19,21 158:4 162:13,16 164:13 165:6 167:20 169:2,4 170:8 171:13 178:1,21 182:22 182:25 185:18,21 193:13,18 194:18 194:23 199:10 204:22 205:1 206:5 208:3 209:4 reporting 118:19 153:13 reports 12:11 102:19,23 103:10 118:21 150:11 198:13,19 200:15 201:3,4,22 202:21	204:8 represent 11:16 19:10 29:6,9,13 49:18 60:9 71:21 72:10,23 155:7,25 162:8 168:24 169:17 183:13 representation 38:17 representatives 102:13 111:1,10 represented 22:17 37:20 38:7 110:16 192:9 request 9:1,6 83:8 83:11 163:9 require 99:7 135:1 required 37:5 43:14 81:13 82:9 97:23 134:22,22 136:6 212:13 requirements 117:13 147:14 190:9 requires 59:25 69:2 79:7 103:2 139:13 resale 120:24 research 15:21 17:1,19 31:9 34:8 107:13,14 researcher 16:19 reserve 126:12 resold 123:4 respect 115:22 120:9 137:3 141:6 143:18 184:17 respectfully 80:15 139:14 respond 181:17 187:21 193:10	response 207:14 responsibilities 181:5 responsibility 174:6 rest 31:21 190:8 restated 94:6 restricted 1:8 result 163:16 164:20 166:11 209:11 resulted 160:13 resume 54:19 retail 11:18 13:11 13:21,25 15:10 17:14 18:2 25:18 26:8 27:15 29:10 32:13,23 36:11 37:1,16,21 38:1,23 39:15 40:10 43:19 44:6 50:14 59:18 65:3 66:8 67:12 68:13 83:15 85:2 89:8 94:11 99:14 114:7 119:24 120:24 121:5,8,11 121:20 122:2,5 123:4 136:1,4 142:12,20,23 144:5,13,14,14,15 146:5 152:23 153:5,6 169:22 170:7,9,25 173:8 174:19 175:22 177:10 188:20 retailer 8:3 13:7 15:8,14,18 17:10 17:11,24 18:6,18 19:17 20:4 21:20 22:1,12 23:4,11,16 23:23 26:15 28:25
--	--	--	---

[retailer - satisfied]

Page 32

29:19,21 30:22 31:20 33:9,17 35:15 36:12,19 37:17 39:8 40:23 41:2,15,23 42:7 43:5 44:4 45:23 46:18 47:6,22 49:8,12,14,22 50:5 50:7,8,13,16 51:17 56:8,11 57:6 60:25 61:8,12 66:5,17,18 67:1 84:23 85:13 88:23 89:12,25 90:4,10 90:16 91:22 94:16 95:14,17,20,21 103:13 134:10,16 143:19,19 144:25 145:6 146:3 169:14 171:17 173:13 176:8 retailers 12:6,12 12:18 14:17 21:14 22:14,18 27:21 33:7 48:2,3,7,15 52:19 58:10 59:3 61:13 66:25 73:13 74:1,8,10,14 75:1 89:16 95:24 96:3 99:12 103:7 123:8 126:7 131:1,5 133:5,11 136:6 143:15 173:21 176:14,17 177:3 177:14,15,21,23 186:17 retrospective 190:19 retrospectively 96:10 190:13,22	return 137:24 210:13,17 returned 138:18 reveal 76:9 180:24 revealed 201:22 revenue 64:1 84:18,20,21 85:3,8 94:10 95:9 132:10 136:24 137:3,13 137:25 138:16,21 148:9 149:5 151:6 173:23 174:5 176:7 177:2 revenues 12:6 48:6 49:18 65:20 103:13 126:25 127:19 132:7,7 135:14 136:15,18 140:24 142:17 144:3 147:25 176:9 review 11:23 12:2 13:1,10 110:25 111:5,9,25 146:2 151:22 202:5 210:7 reviewed 13:6,17 13:19 14:2,13 15:10 16:15 41:24 102:24 109:25 110:3 reviewing 13:5 102:19 rgeman 2:17 right 21:8,16 28:8 41:5,16,25 42:2 44:13 46:2 47:17 54:9 55:25 57:1 58:21 62:7,23,25 62:25 73:9,12 78:21 79:21 83:11	87:17 88:14 104:1 107:23 108:4,17 109:22 110:4,8 112:7 117:24 118:11 119:4 120:6 121:21 122:6,14 127:2 128:10 131:11 132:23 136:23 137:11,13,14 145:1 146:25 150:22,25 151:2,3 152:14 155:9 156:25 157:21 159:3 161:16 162:5,12 169:19 169:23 170:7 172:22 173:22 177:25 179:16 181:6 185:15,17 187:8,14 195:25 197:2 205:7 ringing 91:13 rite 5:10 11:16 41:19 road 5:20 rockett 6:18 rockett.shevon 6:19 role 101:9,14 102:5,17 106:25 107:5 120:9 roles 107:3 rooney 4:18 5:2 rose 4:8 roseland 2:9 ross 4:11 roszel 5:20 roughly 160:13 routinely 107:2	routinized 153:11 153:12,17,18,19 153:22 row 81:24 rows 19:11 ruben 2:3,3 71:18 84:15 87:2 203:3 205:4,12,20 207:11 210:1,2 ruben's 73:9 rule 143:8 ruler 2:13 rules 123:24 124:8 125:5 running 195:3 s s 2:1,21 3:1 4:1 5:1 6:1 7:1 8:1 198:20 211:3 safety 190:9 sagoldberg 3:3 sale 28:21 32:23 43:1 48:4,5 60:22 61:3,9,17 91:4,7 92:1 93:4,14 94:15 96:11,23 97:13,20 134:10 158:12 166:16 167:4 169:18 173:11,11,22 174:21 177:18,19 182:4 sales 30:10 118:3 118:19,21 133:21 134:9 158:23 160:15,18 166:10 sample 110:9,12 sanger 2:11 sas 24:15,17,18,21 satisfied 67:11
---	--	--	--

[satisfies - sir]

Page 33

satisfies 71:11 saying 23:10 47:12 55:7,10 57:20 88:1 91:25 143:25 161:16 185:7 204:15 205:3 says 35:9 73:11 79:21 80:21 85:17 95:9 133:8 136:23 149:22 173:21 198:19 schneider 14:4,6 14:15 sciegen 6:16 sciences 199:15 scope 60:5 67:21 70:19 71:2,12 86:24 139:15 187:20 screen 18:9 28:5 104:20,23 106:7 133:24 200:18 script 35:15 scripts 4:17 34:3 42:5 168:24 scroll 19:20 45:22 second 19:24 26:11 32:10 44:23 44:23 109:13,19 110:10 116:21 156:7 157:1 174:15 198:11,12 seconds 201:20 204:12 secrets 152:1 section 48:22 49:19 61:7 109:1 109:18,19,22 111:19 123:11 security 199:9,16	see 19:12,21 20:9 20:18 21:7 24:22 27:25 31:12,13 42:22 55:19 57:2 77:13,24,24 85:1 88:25 89:8,25 90:16 93:21 108:23 109:18 110:9 111:18,20 112:4 113:14 117:1 122:3,20 128:2,7 130:25 133:7 136:25 138:6 152:2 155:3 159:25 160:2 174:11 195:3 200:16,21 seeing 161:20 seen 131:21 133:22,25 134:2 146:5,12 150:1 152:3,6 202:4 sell 114:2 119:8,21 119:24 121:9 131:15 133:1,14 sellers 75:2 selling 134:15 142:11 sells 92:14 sense 24:13 192:11 sent 20:8 210:14 sentence 14:9 38:7 116:21 117:1 122:15 130:25 133:7 192:22 sentences 132:24 separate 59:6 72:7 94:1 150:8 185:16 195:19 separately 150:3 150:15	september 198:14 series 21:13 served 168:10,16 service 149:12 serving 168:8 199:6,11,13 set 50:7 113:3 139:10 140:6 160:10 179:14 180:7 189:17 209:13 seta 24:22 seth 3:3 11:5 206:13 sets 180:5 setting 23:17 144:6 179:25 settled 166:5 settlement 166:4 seven 97:8 share 104:20,23 106:7 133:24 151:7 shared 104:20,22 105:4 shareholder 12:11 102:19 103:3,9 118:20 shareholders 150:11 153:14 she'd 83:8 sheet 210:11 shelf 146:14 158:21 shevon 6:18 shield 8:6 197:9,12 197:18 198:14 199:22 202:16,22 207:20 ship 121:2	short 54:23 76:1 100:6 103:23 183:8 195:3 shorthand 209:3,8 show 170:2 197:24 198:5 shown 106:3 132:11 shuffling 105:14 side 93:11,13 148:9,9 149:12 200:13,13 sided 142:7 sign 106:5 210:12 signature 209:16 signed 210:20 significant 36:20 114:15 143:12 144:4,8 151:21 155:14 163:19 172:13 significantly 144:13 signing 143:14 similar 104:11 similarly 116:10 simple 23:17 35:19 53:9 54:2 110:24 129:7 simply 26:22 47:21 51:11 70:24 127:8 176:4 single 23:15 25:19 40:20 135:16 202:11 sir 115:19 170:11 171:2 172:3 173:1 173:5 176:2,23 179:20 181:19 188:17 190:23 194:11 196:15,22
--	---	---	--

[sir - state]

Page 34

197:11 sitting 23:11 26:1 37:2 38:2 91:11 158:21 178:5 size 147:9,12 sizes 147:11,18,21 slack 2:11 slater 2:7,7 slaterdavis.com 2:12 slight 144:16,24 slightly 20:18 21:14 121:14 small 116:22 117:4 151:11 smolij 3:5 snippet 14:25 software 24:15,17 solco 3:8,15 sold 27:20 43:7 48:7 84:2,23 85:3 85:13 89:11 95:19 113:11,19,23 114:7,11 118:8,15 119:3 121:11,13 121:19,22,23,24 123:8 128:6 131:17 135:3 138:20 145:13,21 157:4 158:13 159:15 167:5 176:8 187:9 188:19 190:14 solely 17:9 solutions 210:23 somebody 105:14 194:20 sorry 14:10 16:1 17:18 18:15,24 19:5 21:1,22 28:2 35:1,1,10 36:15	41:14 42:19 43:9 45:2 52:8,24 57:11 59:20 62:18 66:21 71:16,18 72:1 75:8 77:11 77:12,21 78:16 85:1 86:2 87:1 91:5 95:5 100:16 104:15 105:13,18 107:25 108:12,16 110:18,20 111:15 113:20 119:12 120:24 128:12 131:24 132:2 140:19 141:25 142:1 148:21 155:12 162:13 164:13,21 165:9 166:21 168:22 169:2 170:15 178:1 183:3 185:19 186:6 187:23 192:21 193:13 194:18 195:13 197:11 199:10 200:19 sort 51:11 53:5,9 53:17 54:9 79:24 101:22 104:10,22 133:22,25 135:23 150:5 202:7 sorting 49:1 sorts 149:7,20 sounds 27:4 183:20 south 3:6 5:8 speak 174:10 180:15 speaking 165:7 special 14:3,14 146:12,13,14	specialty 117:9,16 118:5 121:13 specific 15:9 18:13 18:16 20:21 25:23 26:24 30:10 50:20 61:16 64:2 81:11 101:12 102:8 103:15 104:24 105:11,21 113:24 114:3,3 116:6,7 118:22 119:5 123:12 125:5 132:14,16 135:6 135:20 143:3 151:10 152:17 160:10 161:12 164:24 167:7 184:11,14 185:3,9 194:6 196:15 197:7,20 specifically 15:23 56:13 106:18 113:5 118:21 124:9 196:2 specifics 152:15 196:25 spend 12:23 30:21 102:4 spending 22:14 spent 15:22 30:23 30:25 31:2 68:22 71:21 72:11 101:13 106:16 107:7 108:5,11,19 177:12 178:10 spoiled 145:16 spoke 31:4 spoken 76:13 spreadsheet 8:4 18:7,19 19:11 21:20 22:11 23:3	24:14 31:20 33:9 33:17 49:2 spreadsheets 20:15 st 4:16 staff 20:10,25 22:14 26:15 30:23 30:25 31:4,22 33:2,8,13,16 38:8 38:15 40:8 55:4 76:22 77:1 96:5 195:24 stamp 26:2 207:23 standard 1:13 43:14 196:20 standing 16:4 stanoch 2:22 start 70:5 73:20 109:9 136:15 138:15 142:2 started 41:24 starting 11:25 starts 130:25 state 6:15 19:17 20:23 22:15 23:20 25:21 26:21 27:7 31:25 32:2,12,18 32:19 33:5,10,18 33:22 34:13 35:15 40:15 44:22,25 46:6 47:22 50:14 50:15,17 51:4,6 56:25 58:21,25 59:2,6,19,23 60:8 74:2 123:21 124:2 124:2,2,7,8,17,22 124:23 125:5,8,21 125:22 126:5,11 174:7 181:5 184:11,14,17,18 185:3,9 202:13
--	--	--	--

[state - take]

Page 35

203:23 stated 70:17 71:24 72:14 statement 35:3 68:17 131:9 171:21 202:25 203:3 states 1:1 20:21 21:15 23:14 25:25 33:3 45:23 48:17 50:20,23 51:15 52:17 53:4 54:4 123:23 134:4,25 135:2 165:13 184:3 statistics 12:5,8,9 stats 54:8 stay 109:16 stenotype 209:4 steps 52:2 53:23 53:25 54:4 steven 3:18 steven.hunchuck 3:19 stick 111:16 stipulations 9:9 stocked 172:17,18 stocking 121:25 stomping 27:2 stop 74:14 154:3 175:5 182:16 205:7 stopped 25:14 27:4 storage 117:13 store 150:5 173:17 stored 172:23,25 stores 32:15 172:13 storing 129:25	stoy 6:3 strategy 12:25 103:2 street 2:4,17,24 3:6,13 4:20 5:4,8 6:10,15,19 7:9 strength 192:6 stretch 206:18 strike 13:18 36:1,8 67:6 170:3 178:3 179:8 204:14,17 striking 178:24 structure 141:14 141:17 structures 141:8 141:10 142:24 students 103:3 study 104:5,11,12 studying 13:1 subcategory 22:16 subgroup 74:2 subheading 15:8 15:14 subject 162:5,6 167:23 submit 108:15 submitted 199:20 subscribed 212:14 subsequent 51:8 subsequently 43:7 subset 78:13 113:10,17 114:11 subtotal 51:11 subtract 50:3 subtracted 174:19 subtraction 177:16 suggestion 20:14 suite 2:4,13 3:13 4:5,11,15,20 5:4 7:5,9	sum 47:21 50:12 57:3 58:12 63:1 69:23 summary 55:15 summed 48:19 58:11 73:14 74:14 sums 63:23 super 77:4 supply 103:6,23 106:20 114:18,20 117:9,17 120:1,10 120:17 135:2 136:5 142:13 145:21 172:16 187:10,12,16 190:1,11 191:12 199:16,17 support 175:22 177:16 178:7 179:6 supports 177:10 suppose 67:6,8 supposed 180:24 sure 15:15,16 19:1 19:9,21 24:6 28:3 29:11 31:15 35:24 41:13 45:15 47:18 48:25 54:18 55:9 55:14 56:2,3,7 57:18,20 64:22 66:20 68:24 77:5 82:3 87:22 104:3 109:14 115:12 122:12 134:17 136:16 137:9 140:21 141:4,12 144:17 155:6 160:15 162:21 164:15 189:1,17 193:1 201:13	surmised 34:16 suspect 34:11 switch 118:25 switching 150:23 sworn 212:14 system 106:17 134:5 136:3 147:15 systems 135:1
t			
t 3:12 5:13 8:1 80:23 84:24 85:4 85:14 88:24 89:11 89:13 95:15,20,22 209:1,1 211:3,3 tab 81:15 table 10:1 20:18 20:19 21:7,9,11,11 21:12 45:24 46:19 47:3,6 55:20,21 56:8,12,17,19 58:19,19 59:4,10 59:12,14,14 62:21 63:1 66:3,4,8,10 66:16,18 67:9 68:11 70:11,13 71:20 72:23 73:2 73:12 74:3,6,9,15 74:16 75:1 159:20 168:5 169:14,16 171:19 174:1 tables 59:9 65:24 73:24 74:19 take 44:20 48:13 54:16 75:21 80:13 91:20 92:8 99:23 106:8 120:18,19 120:21 121:1,25 124:16 131:14 158:14 164:25,25 166:14 167:16			

[take - third]

Page 36

178:5 183:4,4	tell 15:21 39:7	38:14 45:20 60:3	things 12:20,22
taken 1:11 22:20	54:7 81:19 97:17	67:19 69:7 70:3,6	57:25 81:7 87:17
54:23 61:14 63:23	102:16 103:24	73:22 82:14 83:2	87:19 90:6 134:20
76:1 100:6 154:15	126:9 157:10,12	84:15 91:8 93:17	137:16 147:13
173:13 183:8	160:11 162:2,22	99:20,21 100:1	149:7,20,24 150:5
203:15 207:22	174:8	101:24 119:18	150:17 167:2
209:6	tend 82:19 147:21	120:15 126:17	172:17 192:22
takes 92:5	153:11	127:21 128:24	201:6
talk 24:25 35:7	term 72:17 81:20	129:15 132:21	think 22:18,24
36:2 55:4 56:19	94:4 148:17 153:2	139:18 162:16	23:10,12 29:5
58:9 85:7 89:21	terminating	163:8 168:1	31:16 38:25 46:13
118:19 132:24	203:16	169:10 170:20	47:20 48:21 51:15
173:7 205:2	terms 17:6 22:5	174:18 175:19	53:8,9 55:8 56:1
talked 13:4 15:6	62:2 63:3 64:18	193:18 208:10	57:17 62:9,13
16:18 21:25 22:11	89:25 90:16 98:19	thanks 84:15	80:16,16 93:14
52:3 83:20 101:8	144:9,10,11 145:5	theoretical 60:24	98:14 99:22
103:7 106:15	145:12 151:6,7,16	64:10,17 65:1	103:11 104:5
129:3 152:19	153:4 164:5	86:9 88:1 89:3,22	105:9 107:4,17,18
160:5 170:4 184:8	testified 20:16	96:2 147:20	109:7 116:5
194:2,15,24	68:3 69:14 156:20	theoretically 65:9	117:25 119:23
talking 22:24 23:2	180:1,4 207:6	theories 21:10	126:18 128:21
23:2 32:14 34:22	testify 179:10	37:12 66:6 73:25	133:23 139:20
41:24 68:23 73:19	193:4	74:5,7,12,17 126:8	140:11,13 141:19
75:9 90:4 93:10	testimony 111:10	184:9	143:6,23 148:10
102:25 118:10	143:22,24 171:3	theory 49:12	148:16 149:24
121:16 139:23	180:22 190:24	50:21 58:25 59:2	150:23,24 152:18
142:17 170:14	192:25 193:2,9	61:10 64:15 65:16	154:2,4 159:12
174:22 178:2	199:20 210:9,18	88:6,6,7,9,20	163:3 176:4
188:8 198:16,17	212:8	90:12,14 128:11	182:18 185:5
199:22	teva 4:6 6:12	128:13 131:11,19	193:3 194:1 195:5
talks 118:7	69:22 103:11	167:1	195:7 199:2
tallied 181:4	118:18 183:13,14	therapeutic 191:4	200:25,25 201:8
teach 16:19	184:1 193:23	191:8,9,14	thinking 106:17
102:17 103:1	194:6,12 206:24	thereof 209:12	107:3
teaching 12:23	206:24	thing 15:20 46:18	third 22:21 49:17
tech 109:6 112:23	teva's 194:9	48:20 59:9 81:3	61:2,11 65:14
113:3 116:15	texas 2:13 4:11	96:3 118:23 128:1	80:20,21 97:11
122:8 130:21	text 205:15,16	146:18,21 148:14	157:10 158:1
technology 150:4	texted 205:14	149:11 173:9	159:14 160:22
telephone 39:20	thank 22:7 28:8	177:18 202:23	163:22 165:16
	34:25 35:11 36:6		167:9,13,17

[third - typically]

Page 37

176:12 181:24 191:25 192:4,9 thornburg 5:7 thought 108:8 145:10 148:22 176:22 three 6:10 68:4 79:25 80:4,9 81:2 81:7 tiffany 4:3 time 1:13 11:1,9 12:23 15:22 24:11 24:25 25:23 26:9 26:11,23 27:10,13 27:20 28:16,18,20 28:22 30:16,21,23 30:25 31:1,2,3,24 35:17,18 37:25 48:13,15 54:20,24 57:5,14 64:6,9 67:5 75:24 76:2 80:14,23 84:24 85:4,14 86:17 88:24 89:11,13 91:15 95:15,20,22 96:19,20 98:10 99:19,22 100:3,9 101:13 102:4 107:8 108:5,14,19 108:25 114:2,14 143:7 144:12 145:15,24 151:18 151:19 152:19,24 154:3,4,12,17 155:16,20 156:15 156:16,17 158:2,6 159:2,3,11 160:9 160:19 162:10 164:5 165:7 167:6 168:1,14 172:24 174:25 183:6,9	187:8 188:17,18 195:3 199:3,4 201:1,9,15 203:15 204:5,6,14,23 206:6,7 209:6 210:19 timeframe 157:5 157:17 158:22 210:8 timer 195:8 times 31:23,23 68:4 83:21 94:1 94:16 95:20 97:8 99:10 156:16 160:7,8 161:20 163:2 184:9 197:1 timestamp 40:1 title 120:21 121:1 123:3 131:14 titled 207:18 today 11:21 33:14 76:6 79:5 104:5 155:9 156:20 178:6 today's 11:25 told 26:18 53:25 58:1 108:13 112:9 114:22,24 127:12 195:10 ton 39:16 tons 37:2 top 19:16 64:14 75:9,14 103:19,25 108:12 110:14 111:2,4 116:12 134:25 148:3 164:10 207:24 topic 195:4 topics 75:19 torrent 69:22	total 35:13 50:12 57:4 58:6,9 67:4 69:23 72:10 73:12 74:13 82:22,23,25 118:19 128:4 181:4 totally 141:17 totals 47:21 touche 117:25 tpp 60:23 tps 133:1 trace 134:3,4,22 135:1 147:15 traced 136:2 track 134:3,4,6,21 134:25 135:11 136:7,11 147:14 147:14 150:10 trade 5:4 121:12 122:2,3,5 123:5 136:1,5 188:21 traded 132:9 trailed 100:17 trained 51:23 54:3 transaction 43:12 96:19 104:24 105:4 127:9 135:9 135:15 137:19,20 143:3 167:7 transactions 23:13 26:1 105:18,20 114:6 179:21 182:4 transcript 210:6 210:20 212:5,8 transcription 209:7 transparency 192:10 traurig 4:2 183:2	treatise 177:9,13 177:15 178:7 179:4,5 trial 71:1 tried 204:9 triple 108:15 true 46:15 180:8 191:24,25 209:7 212:8 try 69:16 77:22 87:11 132:20 183:21 197:4 trying 21:1 22:9 24:5 48:24 51:2,4 53:2,10 78:9 93:18 95:4 102:4 122:12 171:5 182:14,14 189:14 192:24 203:12 turn 15:4 159:20 169:13 207:15,15 turned 26:15 two 20:15 21:10 53:3 55:23 80:8 87:17,19 108:6,9,9 108:11 137:12 142:7,21 153:3,25 162:23 186:1 type 23:4,7 34:15 96:18 118:21 142:9,14 149:3 150:2 151:18,20 152:10 types 78:5,5,25 96:18 105:24 135:3,4 145:14 146:14 152:21 typically 12:21 96:10 98:15 152:8 152:25 179:14 180:7
--	--	---	--

[u.s. - vary]

Page 38

u	141:7 142:22,25	united 1:1 23:14	72:16 96:20 98:4
u.s. 3:9,9,15,15	159:5 164:22	25:25 135:2	176:2 204:10
30:4 37:7 75:3	169:1 174:1,4	165:13	usually 23:21 40:5
102:21 114:1	178:13 179:13	units 89:10 95:19	63:22 97:19 98:17
118:3 124:5	180:13 181:8,18	105:5 118:7 135:3	117:13,15 120:23
135:18 136:1	182:13 186:5	135:17 137:19,20	147:4,24 150:1,14
153:11 158:13	187:23 189:14	147:7,11,13,18,21	
164:7 172:16	192:16 193:1	147:24,24	v
188:21	196:6	universe 37:4	v 210:4 211:1
uh 63:7 85:6	understanding	40:19	212:1
185:21	17:13,25 18:4	university 15:24	valsartan 1:2
ulmer 7:8	22:13 25:2 26:6	16:4,12	24:11 27:9,20,22
ulmer.com 7:9	29:7 40:9 61:8	unjust 20:5,13,17	48:4,6,8 50:9 57:5
ultimate 67:16,17	69:10 92:2 96:9	21:5,12 27:19	71:22 72:12 78:19
139:13	96:12 101:13	47:6 48:3,18 49:9	85:23 86:10 92:11
ultimately 106:22	121:10 122:22	49:13 50:22 58:5	99:15 113:10
158:13 166:3	127:15 134:5,19	58:7,13 59:5,9,17	116:22 117:4
undergrads 54:8	152:1,20 153:24	60:19 61:6,24	118:13 119:1
underlies 52:2	166:2 172:13,22	62:20 63:24 64:11	121:19,22,23
underlying 21:11	179:20 180:6,9	64:24 65:19 74:9	122:19 128:5
26:17 52:13,15	184:21 185:23	84:4,11 115:17,24	131:7 135:24
163:5	understood 17:22	116:5,11 122:18	157:4,18 158:20
underneath 52:13	168:15 190:20,22	122:22 123:19,21	163:16 166:10
95:13	193:3	123:24 124:10,15	169:19 173:22
understand 11:21	uniform 143:13	125:23 126:1,24	186:21 187:9
15:17 19:2 21:2	uninsured 77:10	127:5,8,13,16,18	188:13,19 190:2
21:21 23:10 24:6	77:17 78:11,18	128:11,14 129:3,9	191:3,18 193:5,22
29:5 36:14 39:4	79:6,9 81:11,20,24	130:10 131:12	194:9 210:4 211:1
39:13 41:8 42:13	92:14	133:3,10 149:13	212:1
42:14,14,19 46:2	unit 11:2 54:21,25	169:14,16 171:8	value 129:4,5,7,21
47:18 48:25 51:4	84:22 85:12,21	171:17 184:10	191:4,5,8,9,14,19
53:2,10 55:8,25	86:8 87:13 88:3	unpure 166:11	191:24 192:12
56:3,7 57:18,20,22	89:12 90:19 91:4	unseemly 204:17	vanaskie 14:4,15
58:2 66:3 67:23	91:16 94:16,17	untethered 87:3,7	variable 25:21
71:25 77:6,22	95:21 100:10	upbeat 183:23	81:8
78:15 80:12 86:3	129:24 134:7,25	updated 199:18	variations 144:24
86:25 93:19 94:8	135:12,12,13	upstream 43:24	varied 167:10
95:5,6 97:1,2 99:1	136:9 146:23	150:25 151:16	variety 145:12
102:4 107:2,24	147:1,9,22,23	153:1,25 187:5	199:24
124:7,11 127:7	150:13 154:13,18	use 23:3,6 50:15	various 102:11
134:18 137:8		50:17 55:9 56:2	vary 21:14 124:1
			150:20 153:4

[varying - wholesalers]

Page 39

varying 50:23 verdict 69:5 verify 210:9 veritext 1:10 210:14,23 veritext.com 210:15 version 51:6,8 versions 134:3 185:17,25 188:13 versus 8:6 22:3,3 60:19 125:22 144:25 163:23,25 197:9,13,18 198:15 199:23 202:17 207:20 vial 90:25 91:10 93:6 video 11:6 videographer 7:14 11:1 54:20,24 75:24 76:2 100:3 100:9 132:18 154:12,17 155:16 155:20 183:6,9 201:11,14 videotaped 1:10 view 40:10 123:2 203:15 viewed 176:19 violated 194:12 violation 199:20 virtual 1:10 vis 11:18,18 volume 145:17 148:16	148:21 159:2 waive 208:4 waived 206:24 waiver 76:11 112:13 125:13 walgreens 15:23 15:24,24 16:2,3,7 16:15,21 42:5,16 75:1 104:6,7,12 172:15,24,25 173:3 walk 176:3 walked 206:10 wallack 5:17 155:24 walmart 42:5,16 75:1 walnut 7:9 walsh 6:7,9 walshlaw.com 6:8 6:9 want 11:10 15:4 15:16 20:24 21:4 24:25 27:6,12 29:2,6 34:17 35:7 35:25 36:2 38:18 38:20 44:2,18 45:15 46:3 47:17 55:9 56:2,2,6,14 56:15,21 57:18,19 57:19 58:3 64:22 66:2 68:25 73:11 75:17 77:5,22 84:19 87:11,11 88:21 89:20,20,24 90:15 111:24 113:2,4 116:20 128:1 129:6,7 134:17 142:21 162:20 168:13 180:5 189:17	192:25 201:5,11 205:24 206:3 wanted 13:5 19:9 26:12 37:11 110:24 146:18 168:15 195:4 203:13 wants 132:3 warehouse 120:23 121:3 172:18,24 172:25 warranty 45:24 washington 3:13 4:20 5:14 way 2:13 19:21 43:25 69:3,18 70:21 81:18 98:21 124:16 138:5 146:12 159:13 164:3 165:19 166:8 172:18 198:1 205:5,7 209:11 ways 92:22 133:9 we've 46:13 103:7 140:11 186:17 189:25 194:1 week 97:18 weekend 183:23 weird 14:8 72:2 92:16 went 21:19,24 53:25 97:17 103:22 163:11 181:2 204:4,5 west 4:5 5:4 6:19 7:5 whereof 209:13 whiteley 2:20,21 whitely 38:9 39:11	whitney 6:18 wholesale 104:22 145:19 152:13 164:23 wholesaler 89:5 101:12 102:12,14 104:11,11,19 105:23 110:16 111:1 119:3 122:18 129:17 135:8 136:24 139:10 140:4 141:9,14,16 142:5 144:22 146:2 147:4,13 149:19 150:25 151:12 152:4,16 wholesaler's 101:14 wholesalers 12:6 12:12 100:20 102:5,15,17,20 103:6 104:18 106:6,14,25 107:8 108:7 113:5,13,24 113:25 114:3,12 114:24 115:4,17 115:23 116:11,25 117:7 118:16 119:7,21,25 120:10,18 123:3 123:13 124:16 125:25 126:2 128:10,18 129:10 129:18 130:5,10 130:16 131:13 132:13,25 133:4 133:11,12,23 134:1,6,12,22 135:11,18,21,22 136:6 137:4 142:7
w			
w 3:4,5 wacker 4:5 wait 56:6,18 64:21 126:19 127:22			

[wholesalers - york]

Page 40

142:21 144:1	110:20 112:15,19	160:6 162:1	x
146:5 147:2 151:6	113:22 114:20	165:19	x 1:2,5 8:1
151:15,23 152:7	115:8,12 116:2	work 16:25 17:1	xi01658 209:17
152:22,23,25	119:12 120:15,21	31:18 34:8 38:11	xponent 81:9
wide 118:11,12	121:5 123:1 124:5	101:10,11 102:1	y
william 5:17	124:20 125:2,15	103:21 104:14,17	y'all 154:4
wish 106:11 152:2	126:17 127:21	109:4 112:11	yeah 15:20 27:25
wished 202:20	128:13 129:16	125:11 152:5	28:2,7 33:19
wishes 206:19	130:2,14 132:1,16	207:13	34:24 56:13 62:11
withdraw 72:20	135:14 138:12	working 15:22	66:23 70:8 75:20
73:4 84:10 97:3	139:4,18 140:11	31:3,9 101:15	77:13 80:10 83:12
178:3,16,16 179:3	141:2,19 142:2	103:21 104:7,16	87:20 101:25
195:2 197:3,6	143:23 145:9	108:20,25	105:5 106:11
withdrawing	153:9,18,20,22	works 102:5	108:8 117:8 134:2
175:15,17 178:19	154:6,10 155:12	106:18 135:7	134:11 136:20
178:24	157:21 158:6	152:2	142:5 143:23
witness 2:5 11:7	159:10 162:15,17	world 65:17 68:7	147:3 154:6
14:8 16:3,11 17:4	165:10 167:21	68:8 69:19 70:8	156:11 159:24
17:19 18:12 19:20	168:1,22,25 169:3	72:2 86:9 92:16	165:1 187:22
23:9 24:18 27:1	169:6,10 170:11	152:2 192:14	196:5 201:8
32:6,9 34:2 38:13	171:14 172:2	206:19	203:21 207:3
38:14 39:13 45:4	174:18,24 175:5,9	worries 45:13	year 22:16 23:20
45:21 46:9 49:5	176:2 178:18,23	worry 109:17	25:10,19 26:19
52:8,23 53:15	179:19 180:18	worst 204:12	35:17 40:14 145:3
54:15 57:12 58:18	181:18 183:3	worthless 129:11	153:3,25 161:22
60:3,12,18 62:11	184:8,21 185:5,22	129:13 130:11	184:14
64:5 66:14 67:20	186:5 187:1,22	write 107:19,23	years 106:17
69:7 70:6 71:5,10	189:21 191:7	108:1 117:3	153:3 186:15
71:25 72:15 73:1	193:11,16 194:1	157:22,22 195:12	206:12
74:24 75:13 76:13	194:15 196:5	195:15,20	yell 183:17
76:19 77:13,21	197:24 199:13	writing 107:8	yeller 183:19
79:13 80:3 81:22	202:3,10,14,19,24	108:5	yesterday 13:4
83:10,13,20 85:17	203:23 206:10,15	written 13:18	14:18,23,25 16:19
86:2,14,25 87:15	207:6 209:6,13	127:11 198:19	20:16 29:23 58:1
87:20 88:13 90:3	210:8,10,12,19	wrong 56:4	101:9 106:15
90:19 91:6,9,25	witnesses 13:7,12	wrote 16:6,21	107:16,22 129:4
92:20 96:16 97:8	wmurtha 5:18	113:17 122:16	195:10
97:23 98:12,24	word 55:18 113:17	195:11,21 201:5	yield 69:3
99:17,19,21 100:1	words 78:17 81:2		york 2:18,18 6:20
101:19 104:17	82:20 131:2,3		6:20
105:8,17 107:11	143:7 157:24		

[zhejiant - zooming]

Page 41

z
zhejiant 3:8,15
zhp 69:22
zmick 7:4
zoom 1:10
zooming 70:3

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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Exhibit 49

REDACTED

Page 1

1
2 UNITED STATES DISTRICT COURT
3 FOR THE DISTRICT OF NEW JERSEY
4 MDL No. 2875
5

6 IN RE: VALSARTAN, PRODUCTS)
7 LIABILITY LITIGATION)
8)
9)
10 TESTIMONY OF EXPERT WITNESS)
11 LAURA R. CRAFT)
12)
13)
14)
15)
16)
17)
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19)
20)
21)
22)
23)
24)
25)

February 18, 2022

8:00 a.m.

11
12
13 TRANSCRIPT of the stenographic notes in
14 the above-entitled matter, as taken by and
15 before Sara K. Killian, a Registered
16 Professional Reporter, Certified Court
17 Reporter and Notary Public, remotely via
18 Zoom videoconferencing.
19
20
21
22
23
24
25

<p style="text-align: right;">Page 2</p> <p>1</p> <p>2 A P P E A R A N C E S :</p> <p>3</p> <p>4 KANNER & WHITELEY, LLC</p> <p>5 Attorneys for Plaintiff</p> <p>6 701 Camp Street</p> <p>7 New Orleans, Louisiana 70310</p> <p>8 BY: DAVID STANOCH, ESQ.</p> <p>9 LAYNE HILTON, ESQ.</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14 LEVIN SEDRAN & BERMAN, LLP</p> <p>15 Attorneys for Plaintiffs</p> <p>16 510 Walnut Street, #500</p> <p>17 Philadelphia, Pennsylvania 19106</p> <p>18 BY: CHARLES SCHAFFER, ESQ.</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 4</p> <p>1</p> <p>2 A P P E A R A N C E S:</p> <p>3</p> <p>4 WALSH PIZZI O'REILLY FALANGA</p> <p>5 Attorneys for Teva Pharmaceuticals USA</p> <p>6 1037 Raymond Boulevard, 6th Floor</p> <p>7 Newark, New Jersey 07102</p> <p>8 BY: LIZA WALSH, ESQ.</p> <p>9 CHRISTINE GANNON, ESQ.</p> <p>10</p> <p>11</p> <p>12 MORGAN LEWIS & BOCKIUS, LLP</p> <p>13 Attorneys for Aurobindo Pharma USA, Inc.</p> <p>14 One Oxford Centre, 32nd Floor</p> <p>15 Pittsburgh, Pennsylvania 15219</p> <p>16 BY: STEVEN HUNCHUCK, ESQ.</p> <p>17</p> <p>18</p> <p>19 NORTON ROSE & FULBRIGHT US, LLP</p> <p>20 Attorneys for McKesson</p> <p>21 2200 Ross Avenue, Suite 3600</p> <p>22 Dallas, Texas 75201</p> <p>23 BY: D'LESLI DAVIS, ESQ.</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 3</p> <p>1</p> <p>2 A P P E A R A N C E S:</p> <p>3</p> <p>4 DUANE MORRIS, LLP</p> <p>5 Attorneys for Prinston Pharmaceutical Inc.,</p> <p>6 Zhejiang Huahai Pharmaceutical Co., Ltd.,</p> <p>7 Solco Healthcare US, LLC, Huahai US, Inc.,</p> <p>8 Walmart Stores, Inc., and Walgreen Co.</p> <p>9 1875 N.W. Corporate Boulevard, Suite 300</p> <p>10 Boca Raton, Florida 33431</p> <p>11 BY: DREW DORNER, ESQ.</p> <p>12 SETH GOLDBERG, ESQ.</p> <p>13 DANA KLINGES, ESQ.</p> <p>14 REBECCA BAZAN, ESQ.</p> <p>15 ALEK SMOLIJ, ESQ.</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20 GREENBERG TRAUIG, LLP</p> <p>21 Attorneys for Teva Pharmaceuticals USA</p> <p>22 333 SE 2nd Avenue, Suite 4400</p> <p>23 Miami, Florida 33131</p> <p>24 BY: TIFFANY ANDRAS, ESQ.</p> <p>25</p>	<p style="text-align: right;">Page 5</p> <p>1</p> <p>2 A P P E A R A N C E S:</p> <p>3</p> <p>4 BUCHANAN INGERSOLL & ROONEY, P.C.</p> <p>5 Attorneys for Albertson Companies, LLC</p> <p>6 1700 K Street NW, Suite 300</p> <p>7 Washington, DC 20006</p> <p>8 BY: CHRISTOPHER HENRY, ESQ.</p> <p>9 DAN CAMPBELL, ESQ.</p> <p>10</p> <p>11</p> <p>12 PIETROGALLO GORDON ALFANO BOSCIK & RASPANTI, LLP</p> <p>13 Attorneys for Mylan</p> <p>14 301 Grant Street, 38th Floor</p> <p>15 One Oxford Centre</p> <p>16 Pittsburgh, Pennsylvania 15219</p> <p>17 BY: JASON M. REEFER, ESQ.</p> <p>18</p> <p>19</p> <p>20 BARNES & THORNBURG, LLP</p> <p>21 Attorneys for CVS and Rite Aid</p> <p>22 11 South Meridian Street</p> <p>23 Indianapolis, Indiana 46204</p> <p>24 BY: KARA KAPKE, ESQ.</p> <p>25 JAMES SPRUNG, ESQ.</p>

<div>Page 6</div> <div>1</div> <div>2 A P P E A R A N C E S:</div> <div>3</div> <div>4 ULMER & BERNE, LLP</div> <div>5 Attorneys for AmerisourceBergen Corp.</div> <div>6 600 Vine Street, Suite 2800</div> <div>7 Cincinnati, Ohio 45202</div> <div>8 BY: JEFFREY GEOPPINGER, ESQ.</div> <div>9</div> <div>10</div> <div>11</div> <div>12 DORSEY & WHITNEY, LLP</div> <div>13 Attorneys for OptumRX</div> <div>14 51 West 52nd Street, 9th Floor</div> <div>15 New York, New York 10019</div> <div>16 BY: SHEVRON ROCKETT, ESQ.</div> <div>17</div> <div>18</div> <div>19</div> <div>20 HINSHAW & CULBERTSON, LLP</div> <div>21 Attorneys for Scigen</div> <div>22 53 State Street, 27th Floor</div> <div>23 Boston, Massachusetts 02109</div> <div>24 BY: KATHLEEN E. KELLY, ESQ.</div> <div>25</div>	<div>Page 8</div> <div>1</div> <div>2 I N D E X</div> <div>3</div> <div>4 WITNESS EXAMINATION BY PAGE</div> <div>5 L. Craft Mr. Dorner 9</div> <div>6 Ms. Andras 322</div> <div>7</div> <div>8 E X H I B I T S</div> <div>9 EXHIBITS DESCRIPTION PAGE</div> <div>10 Exhibit 1 Defendants' Amended 14</div> <div>11 Notice of Videotaped</div> <div>12 Deposition of Laura R.</div> <div>13 Craft</div> <div>14 Exhibit 2 Materials Relied Upon 21</div> <div>15 Exhibit 3 Summary of Retail 32</div> <div>16 Pharmacy Data Claims</div> <div>17 Exhibit 4 Expert Declaration of 37</div> <div>18 Laura R. Craft</div> <div>19 Exhibit 5 NDC List of Valsartan 47</div> <div>20 Containing Drugs</div> <div>21 Exhibit 6 On Point Analytics 101</div> <div>22 invoice packet</div> <div>23 Exhibit 7 Class Definitions for 201</div> <div>24 Consumers, Third-Party</div> <div>25 Payors, and Medical</div> <div> Monitoring</div> <div> Exhibit 8 Excel spreadsheet 232</div>
<div>Page 7</div> <div>1</div> <div>2 A P P E A R A N C E S:</div> <div>3</div> <div>4 RIVERO MESTRE, LLP</div> <div>5 Attorneys for MSP RECOVERY LAW FIRM</div> <div>6 2525 Ponce de Leon #1000</div> <div>7 Coral Gables, Florida 33134</div> <div>8 BY: ZALMAN KASS, ESQ.</div> <div>9</div> <div>10</div> <div>11</div> <div>12 HILL WALLACK</div> <div>13 21 Roszel Road</div> <div>14 Princeton, New Jersey 08540</div> <div>15 BY: WILLIAM MURTHA, ESQ.</div> <div>16</div> <div>17</div> <div>18 ALSO PRESENT:</div> <div>19 JUSTIN BILY, Veritext Videographer/Technician</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> <div>25</div>	<div>Page 9</div> <div>1</div> <div>2 THE VIDEOGRAPHER: We are going</div> <div>3 on the record at 8:09 on February 18,</div> <div>4 2022. This is media unit one of the</div> <div>5 video recorded deposition of Laura</div> <div>6 Craft regarding the valsartan</div> <div>7 litigation.</div> <div>8 My name is Justin Bily from the</div> <div>9 firm Veritext and I'm the videographer.</div> <div>10 The court reporter is Sara Killian from</div> <div>11 the same firm.</div> <div>12 All counsel will be noted on</div> <div>13 the stenographic record.</div> <div>14 Will the court reporter please</div> <div>15 swear in the witness and then we can</div> <div>16 begin?</div> <div>17 L A U R A C R A F T, after having first been duly</div> <div>18 sworn, was examined and testified as follows:</div> <div>19 EXAMINATION BY</div> <div>20 MR. DORNER:</div> <div>21 Q. Thank you very much. My name</div> <div>22 is Drew Dorner. I'm counsel to a number of</div> <div>23 entities involved in this case: Princeton</div> <div>24 Pharmaceutical, Zhejiang Huahai</div> <div>25 Pharmaceutical, Solco Healthcare US and</div>

<p style="text-align: right;">Page 10</p> <p>1 L. Craft</p> <p>2 Huahai US.</p> <p>3 Just before we get into this,</p> <p>4 I'll note for the record that this</p> <p>5 deposition is being taken for the purposes</p> <p>6 of discovery and any other purposes allowed</p> <p>7 under the Rules of Civil Procedure and the</p> <p>8 Federal Rules of Evidence.</p> <p>9 So having gotten all of that</p> <p>10 out of the way, Ms. Craft, it's nice to meet</p> <p>11 you.</p> <p>12 Could you please state and</p> <p>13 spell your full name for the record?</p> <p>14 A. Sure. It's Laura, L-A-U-R-A,</p> <p>15 Richards, R-I-C-H-A-R-D-S, Craft C-R-A-F-T.</p> <p>16 Q. Have you been known by any</p> <p>17 other names in the past?</p> <p>18 A. No. Well, prior to 1980, I was</p> <p>19 known simply as Laura Richards.</p> <p>20 Q. Understood. Okay.</p> <p>21 You're here testifying in the</p> <p>22 capacity of an expert in today's case, is</p> <p>23 that right, on behalf of the plaintiffs?</p> <p>24 A. That's correct.</p> <p>25 Q. I understand that you have</p>	<p style="text-align: right;">Page 12</p> <p>1 L. Craft</p> <p>2 let me know that so I can ask it a different</p> <p>3 way or explain it.</p> <p>4 Is that fair?</p> <p>5 A. Yes. I'll be happy to do that.</p> <p>6 Q. Super.</p> <p>7 Then, of course, if I get an</p> <p>8 answer, I'm going to assume that you</p> <p>9 understood the question.</p> <p>10 Can we agree to that?</p> <p>11 A. Yes.</p> <p>12 Q. Okay.</p> <p>13 I am going to try to schedule</p> <p>14 breaks throughout the day today. It is a</p> <p>15 Friday and I don't want to be here any</p> <p>16 longer than anybody else on this call wants</p> <p>17 to be here. I'm sure that includes</p> <p>18 yourself.</p> <p>19 So I'll try to keep them</p> <p>20 somewhat tight, but certainly if there ever</p> <p>21 comes a point where you need to step away,</p> <p>22 that's perfectly fine. I just ask that we</p> <p>23 don't do it while a question is pending.</p> <p>24 Can we agree to that?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 11</p> <p>1 L. Craft</p> <p>2 probably given a number of depositions in</p> <p>3 the past. I saw on your CV there's a few,</p> <p>4 but just give me a sense generally career</p> <p>5 wise of how many depositions do you think</p> <p>6 you've done?</p> <p>7 A. Roughly ten.</p> <p>8 Q. Okay.</p> <p>9 Well, then since we're both</p> <p>10 veterans of the deposition process, I'll try</p> <p>11 not to belabor the point with a bunch of</p> <p>12 protocols and whatnot. I think we're both</p> <p>13 well learned in that.</p> <p>14 In fact, you're actually a</p> <p>15 licensed attorney in the State of</p> <p>16 California; is that right?</p> <p>17 A. That's true.</p> <p>18 Q. Your license is still active?</p> <p>19 A. Yes.</p> <p>20 Q. Okay.</p> <p>21 Well, then, like I said, we</p> <p>22 could skip a lot of the formalities. The</p> <p>23 real important ones that I will restate is</p> <p>24 if there comes a time when you don't</p> <p>25 understand a question that I'm asking, just</p>	<p style="text-align: right;">Page 13</p> <p>1 L. Craft</p> <p>2 Q. Excellent.</p> <p>3 I guess then before we get</p> <p>4 going, do you have any questions for me</p> <p>5 about how this deposition is going to</p> <p>6 proceed today?</p> <p>7 A. No, I don't.</p> <p>8 Q. Okay.</p> <p>9 I will remind everybody on the</p> <p>10 record today -- including you, Ms. Craft, I</p> <p>11 think I'm obliged to notify you as well --</p> <p>12 that any testimony given or documents that</p> <p>13 go electronically between us could be</p> <p>14 subject to the court's protective order. So</p> <p>15 please keep that in mind, anybody who is</p> <p>16 listening in the call, that there's a</p> <p>17 protective order in place and that there's</p> <p>18 going to be information more than likely</p> <p>19 that's going to be exchanged that is subject to</p> <p>20 that protective order.</p> <p>21 So having said all of that,</p> <p>22 let's go ahead -- and Justin, if you could</p> <p>23 pull up the exhibit, it's ID just A as in</p> <p>24 alpha and we could enter that in as Exhibit</p> <p>25 1.</p>

<p style="text-align: right;">Page 14</p> <p>1 L. Craft</p> <p>2 Ms. Craft, I'll let you know,</p> <p>3 so these exhibits, as I understand the</p> <p>4 system, will be uploaded to a confidential</p> <p>5 folder that should be accessible to you and</p> <p>6 to anybody on this video conference. The</p> <p>7 exhibits will also be shown to you on</p> <p>8 your -- I guess your main Zoom screen when</p> <p>9 you look at me and talk -- that one -- so I</p> <p>10 hope that for many of these exhibits the</p> <p>11 video conference tech will be able to sort</p> <p>12 of highlight exactly where I'm talking</p> <p>13 about, but to the extent you need to, you</p> <p>14 can look at that folder if you need to look</p> <p>15 at the entire document.</p> <p>16 Understood? Understand what I</p> <p>17 mean?</p> <p>18 A. Yes.</p> <p>19 (Whereupon, Exhibit 1 was marked for</p> <p>20 identification.)</p> <p>21 Q. Great. Perfect. Thank you.</p> <p>22 I'll ask you this: Exhibit 1,</p> <p>23 have you seen this document before?</p> <p>24 A. I have.</p> <p>25 Q. This is your notice of</p>	<p style="text-align: right;">Page 16</p> <p>1 L. Craft</p> <p>2 with you for the deposition today?</p> <p>3 A. I have a clean copy of my</p> <p>4 report with no annotations and that's it.</p> <p>5 Q. Okay.</p> <p>6 That's the report that you</p> <p>7 submitted -- I want to say the date was</p> <p>8 November 10th of last year?</p> <p>9 A. That's correct.</p> <p>10 Q. Okay. All right.</p> <p>11 Are you taking any drugs or</p> <p>12 medication today that could affect your</p> <p>13 ability to testify, comprehend or remember</p> <p>14 details?</p> <p>15 A. No, I am not.</p> <p>16 Q. Is there anybody in the room</p> <p>17 with you today?</p> <p>18 A. No, there is not.</p> <p>19 Q. Are there any counsel for the</p> <p>20 plaintiffs, I guess, in the building? I see</p> <p>21 it looks like you're in your office, but any</p> <p>22 counsel for the plaintiffs in the building</p> <p>23 near you today?</p> <p>24 A. Not that I know of.</p> <p>25 Q. And I believe we're about 2,500</p>
<p style="text-align: right;">Page 15</p> <p>1 L. Craft</p> <p>2 deposition that brought you here today?</p> <p>3 A. Yes, I believe so.</p> <p>4 Q. Can we go to page four of the</p> <p>5 PDF?</p> <p>6 You'll see there's a series of</p> <p>7 document requests that we made of you. If</p> <p>8 you want to look at them, that's fine, but I</p> <p>9 know you've seen this document before.</p> <p>10 My question is just going to be</p> <p>11 whether or not you personally went through</p> <p>12 these to verify that all responsive</p> <p>13 documents were actually produced to these</p> <p>14 requests, subject to any objections that</p> <p>15 your counsel might have had?</p> <p>16 MR. STANOCH: I'll put an</p> <p>17 objection to the question to the extent</p> <p>18 that there were written objections to</p> <p>19 the deposition notice.</p> <p>20 But go ahead, Ms. Craft.</p> <p>21 A. I didn't actually make the</p> <p>22 production to opposing counsel, but I did</p> <p>23 supply responsive documents to the counsel</p> <p>24 who retained me in this matter.</p> <p>25 Q. Do you have any other notes</p>	<p style="text-align: right;">Page 17</p> <p>1 L. Craft</p> <p>2 to 3,000 miles away. You're coming to us</p> <p>3 from Emeryville, California?</p> <p>4 A. That's correct.</p> <p>5 Q. Okay. Well, hello from</p> <p>6 Washington D.C.</p> <p>7 In terms of electronic devices</p> <p>8 that you have with you, I'm supposing that</p> <p>9 you have a laptop and tablet at least.</p> <p>10 Is that accurate?</p> <p>11 A. I'm viewing you now on a</p> <p>12 desktop. I also have a laptop open to the</p> <p>13 secure document folder and the only other</p> <p>14 electronic device capable of communicating</p> <p>15 is I do have my cell phone in the room.</p> <p>16 Q. Okay. Understood.</p> <p>17 Can we agree that while we're</p> <p>18 on the record you won't send or read any</p> <p>19 communications?</p> <p>20 MR. STANOCH: Objection.</p> <p>21 A. Well, yes. I'm not going to be</p> <p>22 looking at my phone, if that's what you</p> <p>23 mean, or at my email --</p> <p>24 Q. Sure. And --</p> <p>25 A. I'll attempt to hear your</p>

<p style="text-align: right;">Page 18</p> <p>1 L. Craft</p> <p>2 questions and answer them.</p> <p>3 Q. Understood. And I guess I</p> <p>4 should ask that question even better.</p> <p>5 Other than communications shown</p> <p>6 in exhibits and the conversations that we're</p> <p>7 having today, you won't be looking at any</p> <p>8 communications while we're on the record.</p> <p>9 Is that fair?</p> <p>10 A. That's fair.</p> <p>11 Q. Okay.</p> <p>12 What did you do to prepare for</p> <p>13 your deposition today?</p> <p>14 A. I reviewed my report in this</p> <p>15 case, I reviewed Mr. Kosty's report, I</p> <p>16 looked at some of the sources that Mr. Kosty</p> <p>17 had cited in that report and generally</p> <p>18 refreshed my memory about the data that had</p> <p>19 been produced by retailers and plaintiffs in</p> <p>20 this case.</p> <p>21 Q. When you say retailers, are you</p> <p>22 referring to the defendant pharmacies in</p> <p>23 this matter?</p> <p>24 A. I am.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 20</p> <p>1 L. Craft</p> <p>2 So the named plaintiffs, MSP --</p> <p>3 I call them MSP for short -- MSP and MADA,</p> <p>4 their documents that they produced in this</p> <p>5 case? That's what you reviewed in terms of</p> <p>6 plaintiff production?</p> <p>7 A. Yes, that's correct.</p> <p>8 Q. Anything else?</p> <p>9 A. No. That was the basic</p> <p>10 preparation.</p> <p>11 Q. All right.</p> <p>12 I assume you met with counsel,</p> <p>13 but I don't want to put words in your mouth.</p> <p>14 Did you meet with counsel for</p> <p>15 purposes of today's deposition?</p> <p>16 A. I did.</p> <p>17 Q. About how long did you spend</p> <p>18 doing that?</p> <p>19 A. A total of less than four</p> <p>20 hours.</p> <p>21 Q. Does that include your document</p> <p>22 review or was your document review in</p> <p>23 addition to that four-hour timeframe?</p> <p>24 A. My document review was in</p> <p>25 addition to that. That's something I just</p>
<p style="text-align: right;">Page 19</p> <p>1 L. Craft</p> <p>2 A. As well as Humana, which I</p> <p>3 understand is not a defendant, but did</p> <p>4 produce data.</p> <p>5 Q. Then I believe you said</p> <p>6 plaintiffs' productions as well, right?</p> <p>7 A. That's correct.</p> <p>8 Q. What specifically within the</p> <p>9 plaintiff -- well, can you give me a general</p> <p>10 sense of what part of the plaintiffs'</p> <p>11 production you reviewed before today?</p> <p>12 MR. STANOCH: Objection.</p> <p>13 You could try to answer.</p> <p>14 A. I simply skimmed the raw data</p> <p>15 files to remind myself of the field headers,</p> <p>16 the names by which the various elements were</p> <p>17 called out and the general record layouts.</p> <p>18 Q. Okay.</p> <p>19 When you're talking about the</p> <p>20 raw data, was that raw data from MSP</p> <p>21 Recovery claims?</p> <p>22 A. Well, that's one of the</p> <p>23 sources. Of course, MADA has also produced</p> <p>24 data and I reviewed that data.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 21</p> <p>1 L. Craft</p> <p>2 did on my own.</p> <p>3 Q. Okay.</p> <p>4 About how much time did you</p> <p>5 spend looking at documents?</p> <p>6 A. It would be difficult for me to</p> <p>7 estimate because I did this over a period of</p> <p>8 a couple of weeks and I attempted to read</p> <p>9 slowly and thoroughly Mr. Kosty's report and</p> <p>10 materials, but perhaps eight or ten hours.</p> <p>11 Q. I appreciate that.</p> <p>12 When you met with counsel, I</p> <p>13 assume there was nobody from outside On</p> <p>14 Point and the plaintiffs' counsel; is that</p> <p>15 right?</p> <p>16 A. That's correct.</p> <p>17 MR. DORNER: All right. Can we</p> <p>18 please mark and pull up the exhibit</p> <p>19 that is letter B in what was uploaded?</p> <p>20 We'll mark this as Exhibit 2.</p> <p>21 (Whereupon, Exhibit 2 was marked for</p> <p>22 identification.)</p> <p>23 THE WITNESS: This thing has</p> <p>24 kicked me out. I'm now going to sign</p> <p>25 back in to attempt to bring these</p>

<p style="text-align: right;">Page 22</p> <p>1 L. Craft</p> <p>2 documents back up. Hopefully this</p> <p>3 won't continue to be an issue.</p> <p>4 MR. DORNER: Were you able to</p> <p>5 log back in or still working on it?</p> <p>6 THE WITNESS: Yes, I'm here</p> <p>7 now.</p> <p>8 MR. DORNER: Okay. Great.</p> <p>9 Wonderful. Okay.</p> <p>10 The document before you is a</p> <p>11 list -- let's go ahead and go to page</p> <p>12 two, Justin.</p> <p>13 All right.</p> <p>14 Q. This is a list of materials</p> <p>15 that you relied upon in coming up with your</p> <p>16 opinions in this matter, right?</p> <p>17 A. Yes.</p> <p>18 Q. And this list presents a full</p> <p>19 and complete list of every document you</p> <p>20 relied upon to form your opinions?</p> <p>21 A. As of the date of my report,</p> <p>22 yes.</p> <p>23 Q. Okay.</p> <p>24 Actually, I'm glad you brought</p> <p>25 that up.</p>	<p style="text-align: right;">Page 24</p> <p>1 L. Craft</p> <p>2 A. No.</p> <p>3 Q. Okay.</p> <p>4 Are you aware of whether you</p> <p>5 supplied facts to Dr. Conti for purposes of</p> <p>6 her analysis, facts or data?</p> <p>7 MR. STANOCH: Objection.</p> <p>8 Go ahead.</p> <p>9 A. I have no reason to believe</p> <p>10 that anything from my office was supplied to</p> <p>11 Dr. Conti or her staff in connection with</p> <p>12 this case.</p> <p>13 Q. Okay.</p> <p>14 After reviewing Mr. Kosty's</p> <p>15 report, I guess does it affect your opinions</p> <p>16 that you've given in this case in any way?</p> <p>17 A. It certainly does not change my</p> <p>18 opinions in any way. If anything, it</p> <p>19 strengthens them.</p> <p>20 Q. Why is that?</p> <p>21 A. Dr. Kosty -- or Mr. Kosty; I'm</p> <p>22 sorry -- does not dispute or contest the</p> <p>23 basic facts that I lay out in my report. He</p> <p>24 neither contests the simultaneous collection</p> <p>25 of all important data fields to confirm</p>
<p style="text-align: right;">Page 23</p> <p>1 L. Craft</p> <p>2 So other than the documents</p> <p>3 listed in here, have you reviewed any other</p> <p>4 expert materials, be that a report or a</p> <p>5 declaration or expert testimony that's been</p> <p>6 given in this matter?</p> <p>7 A. As I mentioned a moment ago, I</p> <p>8 spent some time reviewing both Mr. Kosty's</p> <p>9 report and some of the materials cited</p> <p>10 therein.</p> <p>11 Q. Okay.</p> <p>12 Other than Mr. Kosty's report</p> <p>13 and the materials that he cited or some of</p> <p>14 the materials that he cited, are there any</p> <p>15 other expert materials that you've looked at</p> <p>16 in this case?</p> <p>17 A. No.</p> <p>18 Q. Okay.</p> <p>19 You haven't reviewed the expert</p> <p>20 report of Dr. Rena Conti?</p> <p>21 A. No. I neither received nor</p> <p>22 reviewed that report.</p> <p>23 Q. Okay.</p> <p>24 And fair to say you didn't</p> <p>25 review her deposition testimony either?</p>	<p style="text-align: right;">Page 25</p> <p>1 L. Craft</p> <p>2 purchases by third-party payers and</p> <p>3 consumers, nor that those electronic files</p> <p>4 are as to their essential elements</p> <p>5 effectively duplicated across multiple</p> <p>6 entities, nor that these data are retained</p> <p>7 for long periods of time, nor that the data</p> <p>8 exists. Although he expresses some</p> <p>9 non-footnoted, non-supported suggestions</p> <p>10 that maybe it will be hard to get the data</p> <p>11 or that working with multi-source data is</p> <p>12 never perfect and is not -- cannot be</p> <p>13 expected to be entirely easy -- two facts</p> <p>14 that I think anyone working with data would</p> <p>15 say apply to all circumstances with</p> <p>16 multi-source data -- he raises no serious</p> <p>17 challenge to the ability to merge data</p> <p>18 across multiple sources and he really limits</p> <p>19 his critique, in my opinion, to the -- in</p> <p>20 any substantive way -- to the question of</p> <p>21 how one identifies state government entities</p> <p>22 and secondarily how one treats the existence</p> <p>23 in pharmacy and PBM records of</p> <p>24 intermediaries who are describes as</p> <p>25 third-party administrators or ASOs to quite</p>

<p style="text-align: right;">Page 26</p> <p>1 L. Craft</p> <p>2 narrow issues that do not in any way</p> <p>3 fundamentally way go to the robustness,</p> <p>4 completeness and accuracy of the data</p> <p>5 identifying class members in this case.</p> <p>6 MR. DORNER: Okay.</p> <p>7 Well, certainly -- I'll preview</p> <p>8 for you that you hit on a lot of the</p> <p>9 issues that I'm sure we'll probably be</p> <p>10 talking about today, so I appreciate</p> <p>11 that rundown and I think we could go</p> <p>12 ahead and move on to some of the other</p> <p>13 material in this case.</p> <p>14 Real quick, though, before we</p> <p>15 take down Exhibit 2, could we go to</p> <p>16 page numbered -- let's start with page</p> <p>17 12. There we go. Thank you, Justin.</p> <p>18 Just for Ms. Craft's sake, flip</p> <p>19 it down -- just spend a couple</p> <p>20 seconds -- 12316 on each page.</p> <p>21 Q. Ms. Craft, I'm showing you</p> <p>22 pages 12 through 15 of your document in the</p> <p>23 Materials Relied Upon list. I'll represent</p> <p>24 to you that these pages reflect various data</p> <p>25 that are from the pharmacies including CVS,</p>	<p style="text-align: right;">Page 28</p> <p>1 L. Craft</p> <p>2 changes.</p> <p>3 I know with regards to the</p> <p>4 Kroger data that we supplied to you a file</p> <p>5 which we had prepared from the raw data,</p> <p>6 which, for example, had a V look up field</p> <p>7 that does not appear in the original, but</p> <p>8 that takes you back to the original entries</p> <p>9 in the Kroger Excel files.</p> <p>10 My recollection is that one or</p> <p>11 more of these files was produced in CSV</p> <p>12 format as opposed to Excel and so we would</p> <p>13 have converted them for the purpose of</p> <p>14 standardizing the presentation of the data</p> <p>15 in a single way that could be then studied</p> <p>16 using this data.</p> <p>17 So the answer is sure, there</p> <p>18 are always some changes and that's why we're</p> <p>19 very careful to produce those intermediate</p> <p>20 files, so you should be able to duplicate</p> <p>21 everything we did.</p> <p>22 Q. Okay.</p> <p>23 The CSV files, were those, by</p> <p>24 chance, from Walmart?</p> <p>25 A. I bet I can tell by looking at</p>
<p style="text-align: right;">Page 27</p> <p>1 L. Craft</p> <p>2 Express Scripts, Humana. Basically, all the</p> <p>3 pharmacy defendants in this case plus</p> <p>4 Humana.</p> <p>5 Do you understand what I mean?</p> <p>6 A. Yes.</p> <p>7 Q. In your back up file that was</p> <p>8 produced to us, I think we got most all of</p> <p>9 these spreadsheets.</p> <p>10 So my first question is the</p> <p>11 files that you sent back to defense counsel,</p> <p>12 were those modified in any way from what was</p> <p>13 provided by the pharmacy defendants and</p> <p>14 Humana?</p> <p>15 A. Well, when you say the files</p> <p>16 that I sent back, as in all data processing</p> <p>17 and analytical exercises, you typically have</p> <p>18 intermediate data sets, for example, in --</p> <p>19 we may have merged time periods into a</p> <p>20 single file. We may have changed formats</p> <p>21 slightly to make the data amenable to</p> <p>22 processing its data, the statistical</p> <p>23 analytic package that we used in this case.</p> <p>24 Exercises such as that result in no</p> <p>25 substantive change to the data, but format</p>	<p style="text-align: right;">Page 29</p> <p>1 L. Craft</p> <p>2 this document that you have up because --</p> <p>3 Q. Page 16.</p> <p>4 A. Yeah.</p> <p>5 Yes, that is correct. The</p> <p>6 Walmart files were produced in CSV format.</p> <p>7 Q. Okay.</p> <p>8 So let me, I guess, make sure</p> <p>9 that I understand your testimony.</p> <p>10 The files that were produced</p> <p>11 back to us as part of your expert report may</p> <p>12 contain some formatting changes or -- I</p> <p>13 guess mostly formatting changes.</p> <p>14 But you didn't add any numbers</p> <p>15 or add anything into those documents when</p> <p>16 you sent them back short of the formatting</p> <p>17 changes.</p> <p>18 Is that accurate?</p> <p>19 A. So we also sent you the files</p> <p>20 that show our analysis of that data. So</p> <p>21 those files then generate results, which is</p> <p>22 added data that we are generating through</p> <p>23 our programmatic treatment of the data. So</p> <p>24 we have -- there's some raw data as it was</p> <p>25 produced by the defendants, there's the</p>

<p style="text-align: right;">Page 30</p> <p>1 L. Craft</p> <p>2 reformatting of that data, which we did, and</p> <p>3 then there's analysis of is that data with</p> <p>4 the outputs that are generated and the code</p> <p>5 that is run to do that analysis and generate</p> <p>6 those outputs.</p> <p>7 We supplied everything except</p> <p>8 the raw data, which I understood had already</p> <p>9 been supplied to you in the course of</p> <p>10 discovery. We may actually have included</p> <p>11 the raw data in its initial format as well.</p> <p>12 I don't recall.</p> <p>13 Q. Okay -- understood. Okay. I</p> <p>14 wasn't referring to the data code or the</p> <p>15 output files I think as you described them,</p> <p>16 but more whatever sort of -- whatever was</p> <p>17 made between the raw data and the output</p> <p>18 files and the code that goes along with</p> <p>19 that, all of that -- those intermediate</p> <p>20 copies -- you're saying that was produced as</p> <p>21 well?</p> <p>22 A. Yes, that's right.</p> <p>23 Q. Okay.</p> <p>24 And that's what's reflected in</p> <p>25 Exhibit 2?</p>	<p style="text-align: right;">Page 32</p> <p>1 L. Craft</p> <p>2 So then the materials relied</p> <p>3 upon reflected in Exhibit 2, that's the raw</p> <p>4 data then that the pharmacies provided; is</p> <p>5 that accurate?</p> <p>6 MR. STANOCH: Objection.</p> <p>7 A. Yes, that's correct.</p> <p>8 MR. DORNER: Okay.</p> <p>9 Can we please pull up -- let's</p> <p>10 mark what's exhibit -- what's labeled C</p> <p>11 in the folder and do that as Exhibit 3</p> <p>12 to today's proceeding.</p> <p>13 We can go past the first page.</p> <p>14 There we go.</p> <p>15 (Whereupon, Exhibit 3 was marked for</p> <p>16 identification.)</p> <p>17 Q. Ms. Craft, this is a summary</p> <p>18 that I understand you generated and included</p> <p>19 as Exhibit E to your expert report that I</p> <p>20 guess purports to show a summary of your</p> <p>21 analysis of retail pharmacy claims data, as</p> <p>22 it says on the top.</p> <p>23 Is that right?</p> <p>24 A. That's right. May I -- this is</p> <p>25 not -- okay. There we go. It was not yet</p>
<p style="text-align: right;">Page 31</p> <p>1 L. Craft</p> <p>2 A. No. When you say Exhibit 2,</p> <p>3 this is document V, right? In my</p> <p>4 materials --</p> <p>5 Q. Yes.</p> <p>6 A. -- the one that's on the</p> <p>7 screen?</p> <p>8 Q. That's right.</p> <p>9 A. No. This is a list of</p> <p>10 materials relied upon. This is not a list</p> <p>11 of our work product. I understand those to</p> <p>12 be two quite different things. Materials</p> <p>13 relied upon are the sources of information</p> <p>14 that the expert incorporates into their</p> <p>15 thinking or their opinion and work product</p> <p>16 is not materials relied upon, but we produce</p> <p>17 it nonetheless to assure that you are able</p> <p>18 to fully understand and replicate each step</p> <p>19 of my process so that you know exactly how I</p> <p>20 got to my conclusions.</p> <p>21 So I would distinguish between</p> <p>22 materials relied upon, which is what we see</p> <p>23 on Exhibit 2, and work product, which we did</p> <p>24 also produce for you.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 33</p> <p>1 L. Craft</p> <p>2 showing up in the folder, but it has</p> <p>3 appeared.</p> <p>4 Okay. Yes, this is the</p> <p>5 activity from my report and does summarize</p> <p>6 the retail pharmacy claims data.</p> <p>7 Q. Okay.</p> <p>8 Other than for the purposes of</p> <p>9 producing this table shown in Exhibit 3, did</p> <p>10 you rely on the pharmacy-produced raw data</p> <p>11 for anything else in coming up with your</p> <p>12 opinion?</p> <p>13 MR. STANOCH: Objection to</p> <p>14 form.</p> <p>15 Go ahead.</p> <p>16 A. Well, I wasn't simply</p> <p>17 attempting to generate the numbers that</p> <p>18 appear in Exhibit E. I was investigating</p> <p>19 the retail data to confirm the adequacy of</p> <p>20 data or of the data that it points to in</p> <p>21 terms of personally identifying information</p> <p>22 with names and addresses and such to</p> <p>23 identify consumer class members who might</p> <p>24 have claims against the pharmacy defendants</p> <p>25 in this case. So this is just one set of</p>

<p style="text-align: right;">Page 34</p> <p>1 L. Craft</p> <p>2 numbers that are generated for illustrative</p> <p>3 purposes out of that data.</p> <p>4 The more important purpose for</p> <p>5 reviewing the retailer data was to confirm</p> <p>6 or investigate my basic understanding that</p> <p>7 when retail pharmacies sell drugs to --</p> <p>8 prescription drugs -- to consumers in the</p> <p>9 US, they carry out their legal obligation to</p> <p>10 record the identity of the person to whom</p> <p>11 the drug is sold and to record the amount</p> <p>12 that that individual has paid towards the</p> <p>13 price of that drug and that they do</p> <p>14 routinely retain those electronic records in</p> <p>15 a form that is accessible and feasible to</p> <p>16 interpret and manipulate.</p> <p>17 That was why I looked at the</p> <p>18 retailer data. These are merely some</p> <p>19 illustrations of what we see in that</p> <p>20 retailer data.</p> <p>21 Q. Okay.</p> <p>22 Now, it's true, though, that</p> <p>23 the retailer data that you looked at that we</p> <p>24 showed in Exhibit 2, that didn't actually</p> <p>25 contain any personal identifying information</p>	<p style="text-align: right;">Page 36</p> <p>1 L. Craft</p> <p>2 those anonymized member IDs.</p> <p>3 Q. Okay. I just want to be clear.</p> <p>4 In the particular data that you</p> <p>5 looked at, there were no actual names or</p> <p>6 states or addresses and no information like</p> <p>7 that? That's true, isn't it?</p> <p>8 MR. STANOCH: Objection to</p> <p>9 form.</p> <p>10 A. No. No. No. You said states.</p> <p>11 Some of the files do include -- for example,</p> <p>12 the ship to state, the member state, the</p> <p>13 retail data generally -- I believe</p> <p>14 invariably -- includes the store number and</p> <p>15 state. So state, yes. Full addresses, no,</p> <p>16 not produced.</p> <p>17 Q. As well as names then, right?</p> <p>18 A. Right. As well as names. But</p> <p>19 that's not because that data doesn't exist.</p> <p>20 MR. DORNER: Okay.</p> <p>21 All right. I think we can put</p> <p>22 Exhibit 3 away. Let's go ahead and</p> <p>23 pull up -- I guess it'll be labeled D</p> <p>24 and mark this as Exhibit 4 to your</p> <p>25 deposition.</p>
<p style="text-align: right;">Page 35</p> <p>1 L. Craft</p> <p>2 of any -- anybody, right?</p> <p>3 A. Right.</p> <p>4 Q. Any individuals?</p> <p>5 A. Yeah. If we're clear about</p> <p>6 what the -- what the word personal identify</p> <p>7 -- or phrase, personal identifying</p> <p>8 information includes, the data with, I</p> <p>9 believe, one exception do include -- and</p> <p>10 that being Kroger -- do include anonymized</p> <p>11 ID numbers for consumers.</p> <p>12 Those anonymized ID numbers,</p> <p>13 whether they are the store's original member</p> <p>14 ID profile for the individual or one that</p> <p>15 has then been transformed to further</p> <p>16 anonymize it, those link directly back to</p> <p>17 the personal profile in the pharmacy's</p> <p>18 records.</p> <p>19 For some of these defendants,</p> <p>20 although they did not populate the fields,</p> <p>21 they do show us very clearly that first</p> <p>22 name, last name, address, state and date of</p> <p>23 birth are included data elements, just as I</p> <p>24 would have expected them to be in the</p> <p>25 pharmacy's data that can be accessed using</p>	<p style="text-align: right;">Page 37</p> <p>1 L. Craft</p> <p>2 (Whereupon, Exhibit 4 was marked for</p> <p>3 identification.)</p> <p>4 Q. All right, Ms. Craft. This is</p> <p>5 a copy of your report that you prepared in</p> <p>6 connection with this case.</p> <p>7 Is that right?</p> <p>8 A. I'm just going to scroll to the</p> <p>9 end. I don't mean to be skeptical, but I</p> <p>10 always like to check to make sure that this</p> <p>11 looks familiar.</p> <p>12 MR. STANOCH: While Ms. Craft</p> <p>13 is doing that, Mr. Dorner, I'm just</p> <p>14 stating for everyone's benefit that in</p> <p>15 the exhibit access folder, the exhibits</p> <p>16 are being named by letter. We have A,</p> <p>17 B, C, D., they are not 1, 2, 3, 4 and I</p> <p>18 don't care which you use -- obviously,</p> <p>19 it's your deposition -- but for the</p> <p>20 benefit of the record, we may want to</p> <p>21 harmonize all that so we know what is</p> <p>22 being referred to later when we read</p> <p>23 the transcript.</p> <p>24 MR. DORNER: Dave, I don't</p> <p>25 think that's a bad idea at all. The</p>

Page 38

1 L. Craft
2 reason for the lettering is because
3 I -- I lettered a number of exhibits
4 today and I hope I don't necessarily
5 have to use them all. But for the sake
6 of telling the court reporter -- excuse
7 me, the video tech -- which exhibit to
8 pull up, they've all got a letter and
9 then I assigned them a number when I
10 enter them. So I'm keeping track as
11 best I can of how the letters
12 correspond to numbers and I have no
13 problem -- shouldn't have a problem
14 harmonizing that at the end of the
15 proceeding, if think that'll be
16 helpful.
17 Fair enough?
18 MR. STANOCH: Definitely.
19 MR. DORNER: Great.
20 Q. Okay. So -- go ahead.
21 A. I believe the question on the
22 floor was whether this was a copy of the
23 report that I had submitted in this matter
24 in November of 2021 and the answer is it's a
25 partial copy of the report that I submitted.

Page 39

1 L. Craft
2 It does not contain any of the exhibits. It
3 goes to the signature page and then does not
4 attach the various exhibits to the report.
5 Q. Understood.
6 I think maybe for today we can
7 call this the narrative portion of your
8 report.
9 Is that okay?
10 A. Sure.
11 Q. Super.
12 Then I also believe you
13 produced a very short errata containing a
14 couple of footnote changes to some
15 citations.
16 Is that right?
17 A. That's correct.
18 Q. Okay.
19 Since finalizing your report,
20 other than the errata that you provided, are
21 there any other changes that you want to
22 make to the substance of the narrative
23 portion of your report?
24 A. Well, the only thing that I
25 would say is as I read it over the last two

Page 40

1 L. Craft
2 weeks in preparation for this deposition, I
3 looked at the code that had been run to
4 generate the minimum count of third-party
5 payors in the class, which is referenced in
6 the report. In running that code and in
7 estimating plans and payors that were
8 specifically identified by IQVIA in the
9 Xponent data, I included all 426 of the NDC
10 codes that had been supplied by counsel and
11 which appear in one of the attachments to
12 this expert report that you have on the
13 screen.
14 And just out of an abundance of
15 caution, I wanted to go back and see if that
16 number would materially change if I
17 restricted the scope of the IQVIA Xponent
18 data to only those NDCs that were
19 manufactured either at API or as a finished
20 product by one of the defendants.
21 So I did update those numbers
22 and using exactly the same code and simply
23 limiting the scope to the at-issue
24 valsartan-containing drugs. The numbers did
25 not, as I expected, materially change.

Page 41

1 L. Craft
2 There were 11,586 plans as opposed to
3 roughly 12,000 as cited in my report and
4 there were 2,949 identified -- separately
5 identified payors on those plans as opposed
6 to roughly 3,000 in my report.
7 But I did want -- so I did do
8 that one additional exercise to just confirm
9 that the numerosity issue had not in any
10 material way changed.
11 Q. Okay. I appreciate you
12 clarifying that.
13 I'd ask are those
14 calculations -- the code and the
15 calculations that you performed, would you
16 be amenable to producing that to us?
17 MR. STANOCH: Objection to
18 form.
19 Go ahead, Ms. Craft, if you
20 want to try to answer that.
21 A. I don't have any problem. It's
22 the exact same code, just applied to a
23 smaller number of NDCs. But I'd be happy to
24 supply it so that you could check for
25 yourself.

<p style="text-align: right;">Page 42</p> <p>1 L. Craft</p> <p>2 Q. Maybe I should ask it a</p> <p>3 different way. Let me ask it a different</p> <p>4 way.</p> <p>5 Do you intend to actually make</p> <p>6 a revision to any portion of your report via</p> <p>7 an attachment or the narrative portion to</p> <p>8 account for this recalculation of TPPs?</p> <p>9 A. I don't -- counsel, I don't</p> <p>10 know legally whether that would be</p> <p>11 appropriate or not. I don't think it's</p> <p>12 necessary. What I said in the report was</p> <p>13 absolutely correct. There's nothing wrong</p> <p>14 with it. It's just as applied to the 426</p> <p>15 NDCs in the dataset -- which I think I make</p> <p>16 explicit -- it's just that I'm supplementing</p> <p>17 that now and telling you that it's roughly</p> <p>18 the same outcome if you limit the NDCs that</p> <p>19 are included in the analysis.</p> <p>20 Q. Okay.</p> <p>21 Can we go to page seven --</p> <p>22 excuse me -- page five of Exhibit 4?</p> <p>23 All right, Ms. Craft.</p> <p>24 So this paragraph here is just</p> <p>25 generally describing the materials you</p>	<p style="text-align: right;">Page 44</p> <p>1 L. Craft</p> <p>2 purity represented and not qualified under</p> <p>3 the FDA generic approvals that had been</p> <p>4 granted for them."</p> <p>5 My first question about that</p> <p>6 passage is just, as a procedural matter, can</p> <p>7 we agree today that for purposes of this</p> <p>8 deposition, VCDs means the at-issue generic</p> <p>9 valsartan, valsartan hydrochlorothiazide,</p> <p>10 amlodipine valsartan and amlodipine</p> <p>11 valsartan hydrochlorothiazide?</p> <p>12 MR. STANOCH: Objection.</p> <p>13 Go ahead.</p> <p>14 A. I would just ask -- I see now</p> <p>15 this Bates has been adjusted, but I had a</p> <p>16 disconnect there because you had directed my</p> <p>17 attention to page one and you were not, in</p> <p>18 fact, reading from page one of my report. I</p> <p>19 did find the text and best as I can catch</p> <p>20 up, I think you read it correctly, but I</p> <p>21 think it's on page two, not page one.</p> <p>22 MR. DORNER: Super. Well,</p> <p>23 let's put page one and two side by side</p> <p>24 then, just so there's no confusion.</p> <p>25 Justin, can you help us out</p>
<p style="text-align: right;">Page 43</p> <p>1 L. Craft</p> <p>2 relied upon. I'm more -- I have the</p> <p>3 question along this line of thinking and</p> <p>4 it's were there documents that you reviewed</p> <p>5 for this case, but you didn't rely on in</p> <p>6 forming in your opinion?</p> <p>7 MR. STANOCH: Objection to</p> <p>8 form.</p> <p>9 Go ahead.</p> <p>10 A. No.</p> <p>11 Q. And it cut out.</p> <p>12 You said no?</p> <p>13 A. I did. I didn't -- yeah. I</p> <p>14 just listed all the documents that I</p> <p>15 reviewed.</p> <p>16 Q. Okay. Thank you.</p> <p>17 All right. Let's go ahead and</p> <p>18 go back to page one of your report.</p> <p>19 A. Okay.</p> <p>20 Q. You're summarizing this case</p> <p>21 saying "Plaintiffs allege that defendants in</p> <p>22 this matter designed, manufactured, labeled,</p> <p>23 marketed, distributed, packaged and sold</p> <p>24 VCDs that were contaminated,</p> <p>25 non-merchantable, not of the quality or</p>	<p style="text-align: right;">Page 45</p> <p>1 L. Craft</p> <p>2 with that?</p> <p>3 Q. Ms. Craft, you're not offering</p> <p>4 an opinion as to the truth of any of the</p> <p>5 allegations that I read and that are</p> <p>6 highlighted on your screen, right?</p> <p>7 MR. STANOCH: Objection.</p> <p>8 Go ahead.</p> <p>9 A. No. I think that's a fair</p> <p>10 statement. I'm not opining as to the</p> <p>11 product quality and any of the legal</p> <p>12 theories behind the claims.</p> <p>13 Q. If we could go and pull up</p> <p>14 paragraph two of your report then put pages</p> <p>15 two and three side by side, this paragraph</p> <p>16 talks about the 428 National Drug Codes or</p> <p>17 NDCs.</p> <p>18 These are the codes that we</p> <p>19 were talking about earlier, a few minutes</p> <p>20 ago, right?</p> <p>21 A. Yes.</p> <p>22 Q. Okay.</p> <p>23 Now in this paragraph, you note</p> <p>24 that you were provided with a list of 428</p> <p>25 National Drug Codes, which uniquely identify</p>

<p style="text-align: right;">Page 46</p> <p>1 L. Craft</p> <p>2 the VCD products that plaintiffs allege to</p> <p>3 have been improperly manufactured and sold</p> <p>4 and to have been both valueless and unsafe.</p> <p>5 Again, you're not offering an</p> <p>6 opinion as to improper manufacturing,</p> <p>7 improper sale, value or safety of the VCDs;</p> <p>8 is that correct?</p> <p>9 A. That is correct.</p> <p>10 Q. Now, I believe you testified a</p> <p>11 minute ago that initially you ran an</p> <p>12 analysis assuming that all 428 of these NDCs</p> <p>13 were, in fact, at issue, but you've since</p> <p>14 clarified that you understand that not all</p> <p>15 428 are, in fact, at issue.</p> <p>16 Is that right?</p> <p>17 MR. STANOCH: Objection to</p> <p>18 form.</p> <p>19 Go ahead.</p> <p>20 A. It is true that the initial</p> <p>21 count for numerosity that I generated was</p> <p>22 generated off of all 428. That's the</p> <p>23 exercise that I repeated prior to this</p> <p>24 deposition, to see whether the results would</p> <p>25 materially change.</p>	<p style="text-align: right;">Page 48</p> <p>1 L. Craft</p> <p>2 below that, it says Mylan manufactured</p> <p>3 drugs.</p> <p>4 You understand all of them to</p> <p>5 be defendants in this case, right?</p> <p>6 A. I do.</p> <p>7 Q. Okay.</p> <p>8 So in the far right column</p> <p>9 where you have NDCs, those are all NDCs that</p> <p>10 you included in both your first and your</p> <p>11 later analysis of -- I think you called it</p> <p>12 numerosity.</p> <p>13 Is that right?</p> <p>14 A. If you're referring to the ones</p> <p>15 on this first page, yes.</p> <p>16 Q. Yeah. That's what I'm</p> <p>17 referring to. Just the first page.</p> <p>18 A. Then the answer is yes.</p> <p>19 Q. Okay.</p> <p>20 Can we scroll down to page two</p> <p>21 of Exhibit 5? Here, we see between rows 58</p> <p>22 and 59 where the entity switches from Mylan</p> <p>23 manufactured drugs to non-defendant drugs.</p> <p>24 Do you see what I'm talking</p> <p>25 about?</p>
<p style="text-align: right;">Page 47</p> <p>1 L. Craft</p> <p>2 In fact, I have to say I don't</p> <p>3 believe it affects any other analysis in my</p> <p>4 report, nor does it affect that conclusion</p> <p>5 about numerosity.</p> <p>6 MR. DORNER: Okay.</p> <p>7 Let's go ahead and pull up the</p> <p>8 document that's prelabeled E as in</p> <p>9 echo, Justin. We'll mark this as</p> <p>10 Exhibit 5.</p> <p>11 (Whereupon, Exhibit 5 was marked for</p> <p>12 identification.)</p> <p>13 Q. All right. Let's do this.</p> <p>14 Here, let's just walk through this,</p> <p>15 Ms. Craft.</p> <p>16 On the screen in front of you</p> <p>17 is, I believe, the list of NDCs that you</p> <p>18 attached to your report as Exhibit B.</p> <p>19 Is that right?</p> <p>20 A. Yes, that looks right.</p> <p>21 Q. Okay.</p> <p>22 If we look on this first page,</p> <p>23 we see under Entity, it's got a number of</p> <p>24 line items for Aurobindo. The next down,</p> <p>25 about row 30, it says Hetero Labs and then</p>	<p style="text-align: right;">Page 49</p> <p>1 L. Craft</p> <p>2 A. I do.</p> <p>3 Q. Okay.</p> <p>4 Where it says non-defendant</p> <p>5 drugs, do you now understand that those NDCs</p> <p>6 associated with those line items are not at</p> <p>7 issue in this litigation?</p> <p>8 MR. STANOCH: Objection to</p> <p>9 form.</p> <p>10 Go ahead.</p> <p>11 A. That is my understanding.</p> <p>12 Q. Okay.</p> <p>13 So if we look at the NDC in row</p> <p>14 58, that NDC would have been included in</p> <p>15 your numerosity analysis both times,</p> <p>16 correct?</p> <p>17 A. That's correct.</p> <p>18 Q. And then row 59 would have only</p> <p>19 been included in your numerosity analysis</p> <p>20 the first time, right?</p> <p>21 A. That's correct.</p> <p>22 MR. DORNER: Okay.</p> <p>23 You could close the call out.</p> <p>24 Leave the exhibit up.</p> <p>25 Q. An NDC -- I want to get your</p>

<p style="text-align: right;">Page 50</p> <p>1 L. Craft</p> <p>2 understanding a little bit about what that</p> <p>3 means.</p> <p>4 An NDC, it doesn't necessarily</p> <p>5 identify the manufacturer of a drug, right?</p> <p>6 MR. STANOCH: Objection to</p> <p>7 form.</p> <p>8 A. It necessarily allows you to</p> <p>9 identify the manufacturer. If the product</p> <p>10 is sold by a relabeler, which has applied</p> <p>11 for its own NDC and is selling using its own</p> <p>12 NDC, then one must link to the application</p> <p>13 for that relabeler to identify the maker of</p> <p>14 the underlying product.</p> <p>15 So it either -- it either</p> <p>16 explicitly tells you who the manufacturer is</p> <p>17 in the first segment of this 11-digit</p> <p>18 code -- the labeler's segment of the code --</p> <p>19 or if the identified labeler in that code is</p> <p>20 merely a relabeler, repackager, then there's</p> <p>21 one more step by going to that application</p> <p>22 to identify the underlying manufacturer of</p> <p>23 the drug product.</p> <p>24 Q. Okay.</p> <p>25 I think I understand -- I'll</p>	<p style="text-align: right;">Page 52</p> <p>1 L. Craft</p> <p>2 and study this schedule and tell you, but</p> <p>3 generally speaking, repackaging and</p> <p>4 relabeling is not going to be the majority</p> <p>5 of this. So no, I can't give you an</p> <p>6 estimated number as I sit here.</p> <p>7 Q. Okay.</p> <p>8 Sort of as a follow on to this</p> <p>9 last set of questions, an NDC also doesn't</p> <p>10 necessarily identify the manufacturer of the</p> <p>11 active pharmaceutical -- back up.</p> <p>12 The NDC does not necessarily</p> <p>13 identify the manufacturer of a drug's active</p> <p>14 pharmaceutical ingredients, does it?</p> <p>15 A. No. That would be in the</p> <p>16 secondary file that I just described a</p> <p>17 moment ago that approves that NDC and</p> <p>18 identifies where the API is coming from.</p> <p>19 Q. I think we could go ahead and</p> <p>20 close this exhibit. Let's go ahead and go</p> <p>21 back to Exhibit 4 at page three.</p> <p>22 Ms. Craft, I want to direct</p> <p>23 your attention -- I realize this is only a</p> <p>24 portion of paragraph two to your report, but</p> <p>25 I think it's in full on page three. It</p>
<p style="text-align: right;">Page 51</p> <p>1 L. Craft</p> <p>2 just try to paraphrase.</p> <p>3 Looking at an NDC, sometimes it</p> <p>4 might actually -- the first three digits</p> <p>5 might actually reflect a manufacturer.</p> <p>6 Other times, you might need to look at an</p> <p>7 additional source or two to figure out who</p> <p>8 the manufacturer is as opposed to a</p> <p>9 relabeler or repackager; is that accurate?</p> <p>10 MR. STANOCH: Objection to</p> <p>11 form.</p> <p>12 A. I wouldn't say two sources. I</p> <p>13 would say one additional source and when you</p> <p>14 say sometimes, I would say that in the vast</p> <p>15 majority of the cases, the first segment of</p> <p>16 this code is, in fact, identifying the</p> <p>17 manufacturer. So it's not a complicated</p> <p>18 exercise, but yes, it is possible and in</p> <p>19 some cases, it will point you to a relabeler</p> <p>20 first.</p> <p>21 Q. Can you put a number on vast</p> <p>22 majority for me as you've used in your last</p> <p>23 answer?</p> <p>24 MR. STANOCH: Objection.</p> <p>25 A. I would -- I could probably sit</p>	<p style="text-align: right;">Page 53</p> <p>1 L. Craft</p> <p>2 says -- here we go. Starting on the -- sort</p> <p>3 of in the middle.</p> <p>4 "Counsel for plaintiffs have</p> <p>5 asked me to evaluate whether, given the</p> <p>6 proposed class definitions and the various</p> <p>7 exclusions applied, it is possible to</p> <p>8 identify the individual consumers and TPPs</p> <p>9 who meet their terms."</p> <p>10 I'll stop reading there.</p> <p>11 My first question is is that</p> <p>12 the full -- what you've described in</p> <p>13 paragraph two, is that the full extent of</p> <p>14 the request that plaintiffs and their</p> <p>15 counsel made to you with respect to class</p> <p>16 certification?</p> <p>17 MR. STANOCH: Objection to</p> <p>18 form.</p> <p>19 A. That's an overarching</p> <p>20 description. If you read on -- it's the</p> <p>21 summary of the opinions -- you will obtain</p> <p>22 further detail about the specific scope of</p> <p>23 my opinions. For example, I note that this</p> <p>24 sentence does not refer to an opinion about</p> <p>25 numerosity, but I clearly express one in</p>

<p style="text-align: right;">Page 54</p> <p>1 L. Craft</p> <p>2 this report and I did so because it was a</p> <p>3 topic that counsel asked me to address.</p> <p>4 Q. Okay.</p> <p>5 So you're offering opinions</p> <p>6 today both on ascertainability and</p> <p>7 numerosity.</p> <p>8 Is that right?</p> <p>9 MR. STANOCH: Objection to</p> <p>10 form.</p> <p>11 A. I'm offering opinions on</p> <p>12 everything that's in this report and both of</p> <p>13 those are.</p> <p>14 Q. Okay.</p> <p>15 Is there anything other than</p> <p>16 those two things?</p> <p>17 MR. STANOCH: Objection to</p> <p>18 form. She just said what her opinions</p> <p>19 are.</p> <p>20 Go ahead.</p> <p>21 MR. DORNER: Let's keep the</p> <p>22 objections to objection to form, as the</p> <p>23 order requires.</p> <p>24 Q. I'm sorry.</p> <p>25 Ms. Craft, do you need to</p>	<p style="text-align: right;">Page 56</p> <p>1 L. Craft</p> <p>2 discusses the application of class</p> <p>3 exclusions and opinion six discusses</p> <p>4 numerosity. Those are the opinions I'm</p> <p>5 offering.</p> <p>6 Q. All right. I appreciate the</p> <p>7 summary. Let me see if I can I guess</p> <p>8 confirm my understanding.</p> <p>9 Would it be fair to say or</p> <p>10 accurate to say that opinions one through</p> <p>11 five relate to the issue of ascertainability</p> <p>12 and opinion six relates to the issue of</p> <p>13 numerosity?</p> <p>14 MR. STANOCH: Objection to</p> <p>15 form.</p> <p>16 Asked and answered.</p> <p>17 Compound.</p> <p>18 Go ahead.</p> <p>19 A. I think all of those issues</p> <p>20 relate to -- yes, one through five relate to</p> <p>21 ascertainability.</p> <p>22 You will note in opinion six</p> <p>23 that what I'm counting here are named plans</p> <p>24 and payors and so this also relates to</p> <p>25 ascertainability, not just numerosity. It</p>
<p style="text-align: right;">Page 55</p> <p>1 L. Craft</p> <p>2 question read back to you?</p> <p>3 A. No, I don't. I do need a</p> <p>4 moment to look at precisely the section I'm</p> <p>5 directing your attention to, which is the</p> <p>6 enumeration of the opinions commencing on</p> <p>7 page six of the report.</p> <p>8 So when you say are you</p> <p>9 limiting your opinions to ascertainability</p> <p>10 and numerosity, I would say ascertainability</p> <p>11 has a number of components to it and there</p> <p>12 are separate opinions relating to those</p> <p>13 components.</p> <p>14 As you see, opinion one relates</p> <p>15 to the function of the NDC. Opinion two</p> <p>16 relates to electronic recordkeeping and the</p> <p>17 legal requirements of the government in the</p> <p>18 United States. Opinion three has to do with</p> <p>19 the Drug Supply Chain Security Act and how</p> <p>20 it encourages the tracing of product</p> <p>21 throughout the supply chain. Opinion four</p> <p>22 discusses both the named plaintiff and</p> <p>23 retailer data and evaluates them along the</p> <p>24 benchmark that I've described for industry</p> <p>25 data generation retention. Opinion five</p>	<p style="text-align: right;">Page 57</p> <p>1 L. Craft</p> <p>2 is not as -- I have not, as Mr. Kosty</p> <p>3 incorrectly suggests -- attempted to say you</p> <p>4 can ascertain the entire TPP class using</p> <p>5 only the IQVIA data. That would be a</p> <p>6 misstatement. I did not at any time suggest</p> <p>7 that that was the case.</p> <p>8 But that doesn't mean that</p> <p>9 having roughly 3,000 of your TPP class</p> <p>10 members identified by plan name and payor</p> <p>11 isn't a big step up in the ascertainability</p> <p>12 process.</p> <p>13 Q. All right. I want to direct</p> <p>14 your attention in paragraph two -- it's the</p> <p>15 same sentence actually.</p> <p>16 The sentence refers to</p> <p>17 individual consumers and TPPs. It doesn't</p> <p>18 make a specific reference to the medical</p> <p>19 monitoring class, so I just want to make</p> <p>20 sure I understand the scope of your opinion.</p> <p>21 Are you included persons who</p> <p>22 would be within the proposed medical</p> <p>23 monitoring class within the term "individual</p> <p>24 consumers"?</p> <p>25 A. Yes.</p>

<p style="text-align: right;">Page 58</p> <p>1 L. Craft</p> <p>2 Q. I think you said yes, but my</p> <p>3 phone cut out.</p> <p>4 A. I did. Yes. I am.</p> <p>5 Q. Okay. Thank you, ma'am. I</p> <p>6 appreciate that.</p> <p>7 Other than numerosity and</p> <p>8 ascertainability, you're not offering any</p> <p>9 other opinions regarding any other element</p> <p>10 of class certification.</p> <p>11 Is that also accurate?</p> <p>12 MR. STANOCH: Objection to form</p> <p>13 to the extent it calls for a legal</p> <p>14 opinion.</p> <p>15 Go ahead, Ms. Craft.</p> <p>16 A. The reason I'm stumbling over</p> <p>17 your questions that ask me generally to</p> <p>18 state which of these opinions relate to</p> <p>19 ascertainability is because I have heard</p> <p>20 lawyers and courts disagree about what that</p> <p>21 word means and I'm not here to express any</p> <p>22 legal opinions about the standards for</p> <p>23 ascertainability.</p> <p>24 So when you ask me to tell you</p> <p>25 whether my opinions are limited to</p>	<p style="text-align: right;">Page 60</p> <p>1 L. Craft</p> <p>2 attempted to further analyze that. I'm</p> <p>3 assuming that paying for a drug that's</p> <p>4 mislabeled or misbranded that is potentially</p> <p>5 harmful that does not conform to warranties</p> <p>6 is an injury and I'm presuming that that</p> <p>7 happened -- I have not investigated the</p> <p>8 contamination claims themselves.</p> <p>9 Q. Okay.</p> <p>10 You're also then assuming</p> <p>11 that -- I want to make sure I get your words</p> <p>12 right -- you're assuming that any VCDs at</p> <p>13 issue in this case were mislabeled or</p> <p>14 misbranded or potentially harmful? Those</p> <p>15 are all assumptions that you're working</p> <p>16 with, right?</p> <p>17 MR. STANOCH: Objection to</p> <p>18 form.</p> <p>19 A. I've been asked to investigate</p> <p>20 whether if plaintiffs claims are valid the</p> <p>21 class that was adversely affected by them</p> <p>22 is -- can be identified. That's what I'm</p> <p>23 expressing an opinion about.</p> <p>24 I said now I think a couple of</p> <p>25 times I did not look into the question of</p>
<p style="text-align: right;">Page 59</p> <p>1 L. Craft</p> <p>2 ascertainability, I can say to you that I</p> <p>3 have expressed opinions here and adduced the</p> <p>4 facts that I believe would be helpful to a</p> <p>5 court in determining the question of</p> <p>6 ascertainability, but what the court will</p> <p>7 consider to be the standard for</p> <p>8 ascertainability is not for me to opine.</p> <p>9 Q. Okay.</p> <p>10 I understand what you're saying</p> <p>11 and I guess let me ask it a different way.</p> <p>12 You're not offering an opinion</p> <p>13 on whether class members -- be they economic</p> <p>14 loss or medical monitoring -- suffered a</p> <p>15 common injury, right?</p> <p>16 MR. STANOCH: Objection to</p> <p>17 form.</p> <p>18 Go ahead.</p> <p>19 A. Well, I am taking as a given --</p> <p>20 in other words, I am assuming for the</p> <p>21 purpose of this exercise that the payment by</p> <p>22 a TPP, a consumer for one of the contested</p> <p>23 VCDs represents an impact or an injury to</p> <p>24 that consumer or that TPP.</p> <p>25 So I have not -- I've not</p>	<p style="text-align: right;">Page 61</p> <p>1 L. Craft</p> <p>2 nitrosamine content or the chemical</p> <p>3 processes by which it got there or questions</p> <p>4 of that sort. I do know that if there were</p> <p>5 differences about which products were</p> <p>6 contaminated and which were not, I would go</p> <p>7 right back to home base, which is the NDCs,</p> <p>8 and I would emphasize again -- and this is</p> <p>9 important for so many aspects of a case like</p> <p>10 this -- that the NDC follows the drug</p> <p>11 product throughout its life and is</p> <p>12 omnipresent as a labeling and tracing</p> <p>13 mechanism.</p> <p>14 So if one wanted to eliminate</p> <p>15 just arbitrarily say ten of these NDCs, one</p> <p>16 could do that. But it's not my job to</p> <p>17 determine which products were affected and</p> <p>18 whether there were any that were not.</p> <p>19 MR. DORNER: Okay.</p> <p>20 We've been going for about an</p> <p>21 hour, so I was going to suggest a</p> <p>22 five-minute break.</p> <p>23 So Dave, Ms. Craft, if you're</p> <p>24 good with that, let's reconvene at</p> <p>25 12:12.</p>

<p style="text-align: right;">Page 62</p> <p>1 L. Craft</p> <p>2 THE WITNESS: Sounds good.</p> <p>3 MR. STANOCH: That's great.</p> <p>4 THE VIDEOGRAPHER: The time is</p> <p>5 9:07.</p> <p>6 This ends media one.</p> <p>7 We're going off the record.</p> <p>8 (Recess taken)</p> <p>9 THE VIDEOGRAPHER: The time is</p> <p>10 9:14.</p> <p>11 This begins media unit two.</p> <p>12 We're back on the record.</p> <p>13 Q. If we could go right back to</p> <p>14 Exhibit 4, paragraph two, page three, I</p> <p>15 think we were just there --</p> <p>16 MR. STANOCH: Again,</p> <p>17 Mr. Dorner, Exhibit 4 is actually</p> <p>18 Exhibit D in the folder, right?</p> <p>19 MR. DORNER: Yes.</p> <p>20 MR. STANOCH: Okay.</p> <p>21 Q. I want to focus on the last</p> <p>22 sentence of this paragraph. It says "This</p> <p>23 declaration identifies the pharmaceutical</p> <p>24 industry practices, legal regulations and</p> <p>25 available data that make it possible to do</p>	<p style="text-align: right;">Page 64</p> <p>1 L. Craft</p> <p>2 MR. STANOCH: Objection to</p> <p>3 form.</p> <p>4 Vague.</p> <p>5 Ambiguous.</p> <p>6 Misstates the report.</p> <p>7 Go ahead, Ms. Craft.</p> <p>8 A. I think those three categories</p> <p>9 are broad enough to encompass the basic</p> <p>10 mechanisms that make it possible to identify</p> <p>11 class members. I obviously have relied upon</p> <p>12 and listed in an exhibit to my report</p> <p>13 sources that I look at that are more</p> <p>14 precise, but I believe -- so for example,</p> <p>15 surveys, information of that sort, I would</p> <p>16 group that under pharmaceutical industry</p> <p>17 practices.</p> <p>18 So as long as we recognize that</p> <p>19 these are broad categories and that they</p> <p>20 encompass a great deal of diverse</p> <p>21 information, then I'm fine with the</p> <p>22 characterization. Something outside of</p> <p>23 this, outside of practices, law, available</p> <p>24 data that I'm generally discussing.</p> <p>25 Q. Honing in on your use of the</p>
<p style="text-align: right;">Page 63</p> <p>1 L. Craft</p> <p>2 so."</p> <p>3 I think "do so" is referring to</p> <p>4 the prior sentence, "It's possible to</p> <p>5 identify the individual consumers and TPPs</p> <p>6 who meet the terms of the proposed class</p> <p>7 definitions."</p> <p>8 Am I understanding that</p> <p>9 correctly, Ms. Craft?</p> <p>10 A. Yes, you are.</p> <p>11 Q. So I want to focus on your</p> <p>12 terms that you used there, pharmaceutical</p> <p>13 industry practices, legal regulations and</p> <p>14 available data.</p> <p>15 Now, I get those are very broad</p> <p>16 terms. I also understand that all three of</p> <p>17 those things are discussed in your report in</p> <p>18 some form or some way. I'll try to ask this</p> <p>19 the best way I know how.</p> <p>20 Other than the pharmaceutical</p> <p>21 industry practices, legal regulations and</p> <p>22 available data that you discuss elsewhere in</p> <p>23 your report, are there any other, I guess,</p> <p>24 bases for your opinions that you're offering</p> <p>25 or is it all confined to those three silos?</p>	<p style="text-align: right;">Page 65</p> <p>1 L. Craft</p> <p>2 term "available data," you're not only</p> <p>3 referring to data that have been produced in</p> <p>4 this case, but also additional data that</p> <p>5 would have to be obtained.</p> <p>6 Is that accurate?</p> <p>7 A. Available data that could be</p> <p>8 obtained. As I mentioned earlier, it is not</p> <p>9 up to me to decide what the court decides</p> <p>10 needs to be produced at particular phases of</p> <p>11 litigation and what the proper standard of</p> <p>12 proof is for ascertainability.</p> <p>13 Q. Okay.</p> <p>14 So let me ask you generally</p> <p>15 what specific data would have to be obtained</p> <p>16 at any point in order to actually produce a</p> <p>17 list of consumer and TPP class members?</p> <p>18 MR. STANOCH: Objection to</p> <p>19 form.</p> <p>20 A. Okay. So I want to start by</p> <p>21 emphasizing as clearly and strongly as I can</p> <p>22 that your question asks what do we need to</p> <p>23 do in order to get a comprehensive list</p> <p>24 prepared and I am not accepting the premise</p> <p>25 that that is the standard for</p>

<p style="text-align: right;">Page 66</p> <p>1 L. Craft</p> <p>2 ascertainability. So to the extent that I</p> <p>3 answer your questions about the preparation</p> <p>4 of a single all encompassing list, I'm</p> <p>5 answering that specific question and I am</p> <p>6 not opining, conceding or assuming that to</p> <p>7 be a necessary step.</p> <p>8 So I want to be very, very</p> <p>9 clear about this and hopefully, with that</p> <p>10 understanding, I won't need to re-emphasize</p> <p>11 this throughout today's deposition.</p> <p>12 Now, with that in mind, to go</p> <p>13 back to your question, which I believe was</p> <p>14 what data would be necessary to compile a</p> <p>15 list of all TPP and consumer class</p> <p>16 members -- am I correct in understanding the</p> <p>17 question?</p> <p>18 Q. I think you've summed it up</p> <p>19 accurately. That's fine. Let's go with</p> <p>20 that.</p> <p>21 A. Okay.</p> <p>22 So the -- at the risk of</p> <p>23 sounding as though I am nitpicking about</p> <p>24 language, the word "necessary" is a problem</p> <p>25 here because there's more than one way to</p>	<p style="text-align: right;">Page 68</p> <p>1 L. Craft</p> <p>2 and I'll try to avoid the word "necessary."</p> <p>3 A. Thank you.</p> <p>4 Q. Exactness is good, so I</p> <p>5 appreciate the clarification.</p> <p>6 Rather than saying that, let me</p> <p>7 ask you -- if you were to -- if you wanted</p> <p>8 to compile a list of all of the consumers</p> <p>9 and the TPPs here, where would you start --</p> <p>10 where would you seek data from? From whom</p> <p>11 would you seek data?</p> <p>12 MR. STANOCH: Objection to</p> <p>13 form.</p> <p>14 Vague -- I'm sorry.</p> <p>15 Are you done, Mr. Dorner?</p> <p>16 MR. DORNER: Yes.</p> <p>17 MR. STANOCH: Objection to</p> <p>18 form.</p> <p>19 Vague.</p> <p>20 Ambiguous.</p> <p>21 Incomplete hypothetical.</p> <p>22 Unintelligible.</p> <p>23 Go ahead, Ms. Craft, if you</p> <p>24 can.</p> <p>25 A. So as laid out in my report, I</p>
<p style="text-align: right;">Page 67</p> <p>1 L. Craft</p> <p>2 skin this cat. There are multiple sources</p> <p>3 of data which can be -- can very easily be</p> <p>4 used in lieu of each other. So there is no</p> <p>5 single source of data that I would consider</p> <p>6 to be essential, which I would take as a</p> <p>7 synonym for your word "necessary."</p> <p>8 There are multiple ways at</p> <p>9 confirming any given transaction and the</p> <p>10 parties to that transaction, meaning the</p> <p>11 third-party payor and the consumer. So I</p> <p>12 would have to say there is no single source</p> <p>13 that is essential.</p> <p>14 As I've laid out in my report,</p> <p>15 there are sources that are more consolidated</p> <p>16 and more uniform and thus more efficient to</p> <p>17 use than other sources, but that does not</p> <p>18 mean that if they were unavailable for some</p> <p>19 reason or otherwise not produced that there</p> <p>20 aren't other sources that can achieve the</p> <p>21 same objective. That's sort of the beauty</p> <p>22 of the pharmaceutical industry, is that</p> <p>23 everybody is recording very similar</p> <p>24 information about a single transaction.</p> <p>25 Q. Let me ask it another way then</p>	<p style="text-align: right;">Page 69</p> <p>1 L. Craft</p> <p>2 consider PBMs to be the single most</p> <p>3 efficient consolidated and uniform source of</p> <p>4 transactional data for prescription</p> <p>5 dispensing and payment in the US and it</p> <p>6 would therefore be my suggestion to start</p> <p>7 there.</p> <p>8 The statistics I cited in my</p> <p>9 report, which are not in any way challenged</p> <p>10 by Mr. Kosty, make clear that currently</p> <p>11 the -- as of 2019, a very small number of</p> <p>12 large PBMs process 96 to 98% of all</p> <p>13 prescription drug claims in the US. So I</p> <p>14 would start by obtaining PBM data, which is</p> <p>15 something that is routinely done in</p> <p>16 pharmaceutical litigation. This is not new</p> <p>17 territory in any way, shape or form.</p> <p>18 With regard to consumer's</p> <p>19 claims against the specific retailers who</p> <p>20 are named as defendants -- so pharmacies who</p> <p>21 are named as defendants in this case -- I</p> <p>22 would -- these are not -- this could be done</p> <p>23 at any point in the process, including</p> <p>24 claims adjudication or even thereafter just</p> <p>25 to address possible disputes about claims.</p>

<p style="text-align: right;">Page 70</p> <p>1 L. Craft</p> <p>2 I would request that the personal</p> <p>3 identifying information withheld by those</p> <p>4 retailer pharmacies in their current</p> <p>5 productions be supplemented. So take those</p> <p>6 records that we already have, we've already</p> <p>7 got the counts of transactions, we've got</p> <p>8 the counts of uniquely identified consumers</p> <p>9 for each of the defendants and I would say</p> <p>10 now give me the names, the home addresses,</p> <p>11 the dates of birth, the identifying</p> <p>12 information associated with those files and</p> <p>13 the deposition testimony of the retailer</p> <p>14 defendants makes quite plain that they</p> <p>15 certainly could do that.</p> <p>16 So that would address -- that</p> <p>17 would fill out and virtually complete the</p> <p>18 claims data that would be relevant as to the</p> <p>19 retailers since TPPs do not have claims</p> <p>20 directly against the retailers.</p> <p>21 Once I had the PBM data, if</p> <p>22 indeed a court concluded that it were --</p> <p>23 that it was necessary to comprehensively</p> <p>24 resolve instances where the PBM client is</p> <p>25 listed as a -- is an ASO or a TPA, which is</p>	<p style="text-align: right;">Page 72</p> <p>1 L. Craft</p> <p>2 that data not only exists electronically,</p> <p>3 that it can be accessed programmatically and</p> <p>4 that it is accurate enough to meet both</p> <p>5 regulatory standards, as in reporting to</p> <p>6 insurance commissioners, and to bill each</p> <p>7 and every self-funded client who is</p> <p>8 responsible for the payment of benefits and</p> <p>9 to do so correctly.</p> <p>10 So those would be the initial</p> <p>11 sources that one would consult, assuming</p> <p>12 that one wanted to -- rather than simply</p> <p>13 identifying a plan, an identified client who</p> <p>14 delivers the money to the PBM, but to</p> <p>15 actually drill down and sort out which of</p> <p>16 those have a separate underlying</p> <p>17 self-funding plan sponsor.</p> <p>18 I want to point out, again,</p> <p>19 that PBMs frequently produce their claims</p> <p>20 data with indications in either the account</p> <p>21 or group file -- group field saying TPA or</p> <p>22 ASO, but they do not invariably do so.</p> <p>23 Those are some places that I</p> <p>24 would suggest be tapped to dig into this</p> <p>25 reservoir of redundant and comprehensive and</p>
<p style="text-align: right;">Page 71</p> <p>1 L. Craft</p> <p>2 to say an intermediary acting on behalf of</p> <p>3 the underlying payor, I would first request</p> <p>4 that the PBMs produce their plan set of</p> <p>5 worksheets or other data that identifies</p> <p>6 whether the particular plan and group are</p> <p>7 being handled by an intermediary or whether</p> <p>8 the client represents the underlying payor.</p> <p>9 An alternative is to go</p> <p>10 directly to the largest insurers in this</p> <p>11 country and it's not as though we don't know</p> <p>12 who they are. They are in numerous reports</p> <p>13 and -- do we have someone who needs to mute</p> <p>14 here? I'm getting -- okay -- and supply</p> <p>15 them with the list of plans and groups that</p> <p>16 they are listed as clients for and ask them</p> <p>17 to identify which are ASOs and which are</p> <p>18 TPAs and -- ASOs or TPAs and which, on the</p> <p>19 contrary, are their own fully insured risk.</p> <p>20 This is not a difficult</p> <p>21 process. Every financial report that those</p> <p>22 entities generate must be able automatically</p> <p>23 to segregate those accounts and their</p> <p>24 associated revenue and expenses.</p> <p>25 So there is no question that</p>	<p style="text-align: right;">Page 73</p> <p>1 L. Craft</p> <p>2 have accurate electronic data.</p> <p>3 Q. I appreciate the rundown and</p> <p>4 again, I think these are all topics that</p> <p>5 we're going to probably get to. If you'll</p> <p>6 indulge me just a moment, I just want to</p> <p>7 look at my notes on that.</p> <p>8 A. Sure.</p> <p>9 Q. So the process -- the initial</p> <p>10 steps I think you called them that you just</p> <p>11 described in your last answer, is that a</p> <p>12 process that you've actually done or</p> <p>13 overseen before?</p> <p>14 MR. STANOCH: Objection to</p> <p>15 form.</p> <p>16 Go ahead.</p> <p>17 A. Well, I talked about three</p> <p>18 different data sources there. So I'm not</p> <p>19 sure what part of that process you're</p> <p>20 talking about. I'm not clear about your</p> <p>21 question.</p> <p>22 Q. Okay. I'll try and rephrase.</p> <p>23 Have you ever -- let me back</p> <p>24 up.</p> <p>25 You said you would start by</p>

<p style="text-align: right;">Page 74</p> <p>1 L. Craft</p> <p>2 obtaining PBM data because they're the -- I</p> <p>3 think "most efficient" was your</p> <p>4 characterization.</p> <p>5 With regard to claims by</p> <p>6 consumers against retailers, you would ask</p> <p>7 for a supplementation of their already</p> <p>8 produced information to include PII or</p> <p>9 personally identifiable information and then</p> <p>10 once you had PBM data, you would resolve</p> <p>11 instances where a PBM's client is an ASO or</p> <p>12 TPA or fully insured by asking the PBMs to</p> <p>13 produce their plan set up worksheets.</p> <p>14 Is that an accurate</p> <p>15 characterization of the three sources you</p> <p>16 talked about?</p> <p>17 MR. STANOCH: Objection to</p> <p>18 form.</p> <p>19 Misstates testimony.</p> <p>20 Vague.</p> <p>21 Ambiguous.</p> <p>22 Compound.</p> <p>23 Go ahead.</p> <p>24 A. Well, you skipped the last</p> <p>25 part, which was to literally send to</p>	<p style="text-align: right;">Page 76</p> <p>1 L. Craft</p> <p>2 and the consumer.</p> <p>3 So all of those facts that one</p> <p>4 might suppose to be of interest to</p> <p>5 defendants -- representing defendants in a</p> <p>6 case like this -- would be fully known</p> <p>7 regardless of the resolution of the ASO, TPA</p> <p>8 issue.</p> <p>9 So it's not as though there's a</p> <p>10 question about the nature or the substance</p> <p>11 or the enforceability of the claim. The</p> <p>12 issue is merely the administrative one of do</p> <p>13 we need to know whether the representative,</p> <p>14 who is an ASO, is the one to assert the</p> <p>15 claim or whether the underlying funder is.</p> <p>16 In other words, you want to put</p> <p>17 a name in that blank that says and there is</p> <p>18 a self-funded entity underneath this. I'm</p> <p>19 merely saying I am expressing no opinion</p> <p>20 that that is a necessary step. I am -- I</p> <p>21 don't -- I will confess to you that I am</p> <p>22 confused about why that's even relevant to</p> <p>23 the ability to properly define a class and</p> <p>24 to -- for defendants to properly represent</p> <p>25 themselves in a case like this. But I am</p>
<p style="text-align: right;">Page 75</p> <p>1 L. Craft</p> <p>2 insurers a list of the plans and groups for</p> <p>3 which they are recorded as clients in the</p> <p>4 PBM data and say tell us which are</p> <p>5 self-funded by the plan sponsor which you</p> <p>6 insure. For those self-funded, tell us the</p> <p>7 funder's name.</p> <p>8 So you left that part out.</p> <p>9 Then the other thing is that I</p> <p>10 do just once again want to make clear that</p> <p>11 when you say you would get down to resolving</p> <p>12 this question about the intermediaries, the</p> <p>13 ASO or TPA, I think I was quite careful in</p> <p>14 my statement to say if someone -- if a court</p> <p>15 determined that that was necessary.</p> <p>16 I want to stress that the</p> <p>17 reason for that proviso is it is not as</p> <p>18 though if faced with the PBM data the</p> <p>19 defendants don't know exactly how many</p> <p>20 prescriptions were paid for by a given plan</p> <p>21 and exactly how much was paid for those</p> <p>22 prescriptions, where they took place, when</p> <p>23 they took place, what was dispensed, what</p> <p>24 the total price was, what the allocation of</p> <p>25 the price was between the third-party payer</p>	<p style="text-align: right;">Page 77</p> <p>1 L. Craft</p> <p>2 saying that if it decided -- if a court said</p> <p>3 you need to do that, there are ways to do</p> <p>4 it.</p> <p>5 Q. Okay. Let me -- I appreciate</p> <p>6 the clarification. You are right. I did</p> <p>7 leave out -- I guess I could call it number</p> <p>8 of four, asking insurers directly. You're</p> <p>9 right. I forgot and thank you for clearing</p> <p>10 it up. Let me break it down then.</p> <p>11 Have you obtained -- the first</p> <p>12 source of data was PBM data.</p> <p>13 Have you actually reached out</p> <p>14 in the past to a PBM and obtained the sort</p> <p>15 of data that you would obtain for this case</p> <p>16 to identify class members?</p> <p>17 MR. STANOCH: Objection to</p> <p>18 form.</p> <p>19 Go ahead.</p> <p>20 A. Over and over and over again,</p> <p>21 yes. I am frequently involved in preparing</p> <p>22 requests for PBM data, defining fields that</p> <p>23 would be sought in PBM data, reviewing PBM</p> <p>24 sample productions to see how they conform</p> <p>25 with those requests and then utilizing in</p>

<p style="text-align: right;">Page 78</p> <p>1 L. Craft</p> <p>2 one way or another whatever data is</p> <p>3 produced. So yes, I am -- I do not</p> <p>4 individually sit down and discuss this with</p> <p>5 PBMs. I am always working through counsel,</p> <p>6 but I work on that process regularly.</p> <p>7 Q. Okay.</p> <p>8 Second source of data. PII to</p> <p>9 supplement the pharmacy productions that are</p> <p>10 already expent in this case.</p> <p>11 Have you made such a request to</p> <p>12 pharmacy defendants in the past?</p> <p>13 A. Yes, I have worked on</p> <p>14 litigation where individual consumers ended</p> <p>15 up being identified and although I don't</p> <p>16 consider it particularly relevant because in</p> <p>17 this case the retailer defendants have</p> <p>18 themselves said in their declarations that</p> <p>19 they have that data and could produce that</p> <p>20 data if ultimately ordered to do so in a</p> <p>21 HIPAA compliant order.</p> <p>22 Q. Third source, asking PBMs to</p> <p>23 provide their plan set up worksheets, I</p> <p>24 believe.</p> <p>25 Let's assume for purposes of</p>	<p style="text-align: right;">Page 80</p> <p>1 L. Craft</p> <p>2 the detail which some of which may be viewed</p> <p>3 as confidential. In those plan set up</p> <p>4 worksheets, there's lots and lots of benefit</p> <p>5 structure information that is completely</p> <p>6 irrelevant to this case that is contained in</p> <p>7 those records.</p> <p>8 We're merely here examining the</p> <p>9 question if you had to figure out whether</p> <p>10 the PBM's client was an ASO versus a</p> <p>11 self-funding payor, then we would be looking</p> <p>12 for that capacity designation and that is</p> <p>13 electronic data. So when I say plan set up</p> <p>14 worksheet, I want to make clear I don't mean</p> <p>15 a piece of paper that somebody wrote in on</p> <p>16 in pen. I mean electronic data that</p> <p>17 includes that information.</p> <p>18 In some cases, PBMs are, as I</p> <p>19 said, recording that very type of</p> <p>20 classification in the claims data that we</p> <p>21 see produced. You see an ASO or TPA</p> <p>22 designation. In other cases, that</p> <p>23 designation may not be apparent in the</p> <p>24 claims data, but may be linked to the group</p> <p>25 number that helps to segregate claims, for</p>
<p style="text-align: right;">Page 79</p> <p>1 L. Craft</p> <p>2 this question that it has been deemed</p> <p>3 necessary, as you point out.</p> <p>4 Okay?</p> <p>5 MR. STANOCH: Objection to</p> <p>6 form.</p> <p>7 Q. Third source, PBM plan set up</p> <p>8 worksheets.</p> <p>9 Have you obtained plan set up</p> <p>10 worksheets from PBMs for the purpose of</p> <p>11 excluding ASO providers and third-party</p> <p>12 administrators?</p> <p>13 MR. STANOCH: Objection to</p> <p>14 form.</p> <p>15 Vague.</p> <p>16 Ambiguous.</p> <p>17 Asked and answered.</p> <p>18 Incomplete hypothetical.</p> <p>19 Go ahead.</p> <p>20 A. So I want to clarify that -- if</p> <p>21 I left the impression that one would</p> <p>22 actually need the plan set up worksheet as</p> <p>23 opposed to merely the payor identification</p> <p>24 from that sheet, then I want to clarify that</p> <p>25 because it's not as though we need all of</p>	<p style="text-align: right;">Page 81</p> <p>1 L. Craft</p> <p>2 example, for a single big insurer such as a</p> <p>3 Blue Shield and there may be separate</p> <p>4 groups.</p> <p>5 So whether -- I have not had a</p> <p>6 case where these worksheets, these plan set</p> <p>7 up worksheets have been produced, but I</p> <p>8 know, as does Mr. Kosty -- and he says this</p> <p>9 in his report -- that those data exist.</p> <p>10 Q. Fair to say then that you've</p> <p>11 never undertaken a review of these sort</p> <p>12 of -- let me back up because I want to take</p> <p>13 account of your explanation that you don't</p> <p>14 need the whole thing.</p> <p>15 I think you said there's</p> <p>16 certain, you know, benefit packages and I</p> <p>17 want to take account of that because I think</p> <p>18 it's immaterial to my question. So I'll try</p> <p>19 to ask this the right way.</p> <p>20 If I'm understanding you</p> <p>21 correctly, you have not had occasion in the</p> <p>22 past to review the portion of set up</p> <p>23 worksheets relating to identifying an ASO or</p> <p>24 a TPA role? You've not had occasion to do</p> <p>25 that in the past in connection with</p>

<p style="text-align: right;">Page 82</p> <p>1 L. Craft</p> <p>2 excluding ASO or TPA entities from a class;</p> <p>3 is that accurate?</p> <p>4 MR. STANOCH: Objection to</p> <p>5 form.</p> <p>6 Vague.</p> <p>7 Ambiguous.</p> <p>8 Misstates prior testimony.</p> <p>9 Compound.</p> <p>10 Unintelligible.</p> <p>11 Go ahead.</p> <p>12 A. That's not a process I've been</p> <p>13 asked to perform.</p> <p>14 Q. Okay.</p> <p>15 Then you also mentioned -- I</p> <p>16 want to make sure I get it right -- in other</p> <p>17 cases, it being the existence of an ASO or a</p> <p>18 TPA relationship, it may be linked to group</p> <p>19 number is what I wrote down, but -- am I</p> <p>20 characterizing your testimony right?</p> <p>21 MR. STANOCH: Objection to</p> <p>22 form.</p> <p>23 Go ahead.</p> <p>24 A. Yes. You've got that right,</p> <p>25 which is to say that there are a number of</p>	<p style="text-align: right;">Page 84</p> <p>1 L. Craft</p> <p>2 data. It's not coming from another source</p> <p>3 for them. They're getting it from their</p> <p>4 PBM. So that data must be structured in a</p> <p>5 way that allows for such segregation. I've</p> <p>6 seen that done in different way, but it is</p> <p>7 an essential business function.</p> <p>8 MR. DORNER: Okay.</p> <p>9 I want to move on. I think we</p> <p>10 might get into a little bit more of the</p> <p>11 nitty-gritty on this later. I do want</p> <p>12 to go ahead and move on to other</p> <p>13 aspects of your report.</p> <p>14 I guess this is sort of</p> <p>15 related. In your report -- actually,</p> <p>16 lest go to your report, paragraph five,</p> <p>17 Exhibit 4, paragraph five.</p> <p>18 Sorry, Justin. I should have</p> <p>19 told you to leave that up.</p> <p>20 Q. This paragraph lists the number</p> <p>21 of cases that you have been involved with, I</p> <p>22 think, in the last four years. I want to</p> <p>23 focus on two of them in particular. One is</p> <p>24 the in re: -- I'm going to butcher this --</p> <p>25 Suboxone case.</p>
<p style="text-align: right;">Page 83</p> <p>1 L. Craft</p> <p>2 ways that a large insurer that operates both</p> <p>3 to provide fully insured benefits and also</p> <p>4 operates as a service provider, may ask that</p> <p>5 its data be segregated so that it can do two</p> <p>6 things: One, divide those claims that it is</p> <p>7 responsible for paying, i.e. those where it</p> <p>8 is the insurer, from those that it will be</p> <p>9 billing to an underlying client, and second,</p> <p>10 properly link those administrative claims to</p> <p>11 the client who will have to be billed for</p> <p>12 them.</p> <p>13 It's important to just</p> <p>14 understand the practical reality here that</p> <p>15 when the insurer receives data that includes</p> <p>16 data for claims related to ASO clients, it</p> <p>17 has to be able to push a button and bill</p> <p>18 those exact claims to each of its clients</p> <p>19 correctly.</p> <p>20 That requires that the data be</p> <p>21 segregable based upon the underlying ASO</p> <p>22 client. You can't do this business if</p> <p>23 that's not true because the data that the</p> <p>24 ASO is receiving from -- and that it's using</p> <p>25 to bill its clients is this very same PBM</p>	<p style="text-align: right;">Page 85</p> <p>1 L. Craft</p> <p>2 Am I pronouncing that correct?</p> <p>3 A. Yes.</p> <p>4 Q. Thank you.</p> <p>5 In that case, I believe you</p> <p>6 gave an opinion on ascertainability in that</p> <p>7 case; is that correct?</p> <p>8 MR. STANOCH: Objection.</p> <p>9 Go ahead.</p> <p>10 Q. Let me rephrase.</p> <p>11 You gave an opinion with</p> <p>12 respect to identifying class members in that</p> <p>13 case.</p> <p>14 Is that accurate?</p> <p>15 A. It was a very narrow opinion.</p> <p>16 If you've read the report, you know that it</p> <p>17 was -- it was a very narrow and very brief</p> <p>18 report. But it was relevant to the question</p> <p>19 of assembling a list of class members.</p> <p>20 Q. Okay.</p> <p>21 And admittedly, Ms. Craft, I've</p> <p>22 not read that document. I'm not even sure I</p> <p>23 have access to your report for that case,</p> <p>24 so -- and that's neither here nor there.</p> <p>25 All I want to ask is as I</p>

Page 86

1 L. Craft
2 understand that case, I believe any opinion
3 that you gave was not challenged in that
4 matter.
5 Is that accurate?
6 A. I have no idea whether that's
7 true or not. I don't --
8 Q. Okay.
9 A. -- spend my time tracking what
10 people say about opinions.
11 Q. I guess that's what we do, huh?
12 So that's really all I wanted
13 to know about that case. The other case is
14 Niaspan, which is down two lines. Niaspan
15 Antitrust litigation.
16 Do you see the one I'm
17 referring to?
18 A. I do.
19 Q. In that case, I believe you
20 also gave an opinion with respect to
21 identifying third-party payors and
22 separating out ASOs, TPAs and fully insured
23 plans from that class because those three
24 entities were excluded.
25 Am I characterizing that

Page 87

1 L. Craft
2 accurate?
3 MR. STANOCH: Objection.
4 I just caution the witness not
5 to divulge any information to the
6 extent it's subject to a protective
7 order in that case.
8 But please, you may answer.
9 A. Yes, I think that's a correct
10 characterization. In that case, the class
11 definition involved an explicit exclusion
12 for fully insured plans which is not present
13 here and that was the one topic that was
14 addressed in the course of my reports.
15 Q. Now, I believe, though, that
16 you say later in your report that fully
17 insured plans would not be TPPs in this
18 case.
19 Isn't that right?
20 A. Absolutely. And as I made
21 clear in that language, that's not because
22 there's an exclusion that one needs to then
23 identify all of those falling within the
24 exclusion and take them out of the class.
25 It is because the initial qualifying

Page 88

1 L. Craft
2 condition for class membership is the
3 payment for one of the challenged VCDs and
4 in the case of a fully insured health plan,
5 that condition is never met because they
6 don't pay for the benefits that are supplied
7 to their members or enrollees.
8 So there's no reason in the
9 world to go out attempting to identify those
10 entities because they're not the payor in
11 the first place. They fail to meet that
12 initial qualifying threshold.
13 Q. The effect, though, is the
14 same. Whether an entity is excluded or it's
15 just not included in the first place, a
16 fully insured plan in this case I believe
17 you're saying would not be included from the
18 get go, right?
19 MR. STANOCH: Objection to
20 form.
21 Vague.
22 Ambiguous.
23 Misstates testimony.
24 Go ahead.
25 A. Yes. We have to be very

Page 89

1 L. Craft
2 careful about the language here because you
3 said a fully insured plan would not be
4 included within the get go. So first of
5 all, class members are not plans. Class
6 members are payors in the TPP class and
7 that's a critical distinction.
8 Second, the TPP -- the payor on
9 that plan is a class member. That's the
10 insurance company. So the insurance company
11 that provides the coverage is a member of
12 the class, has paid for the claims and
13 that's what we need to know. We're trying
14 to identify those insurance payors who are
15 providing the benefits under fully insured
16 plans.
17 So I don't think that I would
18 quite agree with your characterization
19 that's the same thing one way or another.
20 There is simply no need to go through the
21 roughly 88% of employer plans that fully
22 ensure their benefits and figure out who the
23 sponsors are on all of those plans. Those
24 sponsors are not payors. They're not
25 relevant to the class definition.

<p style="text-align: right;">Page 90</p> <p>1 L. Craft</p> <p>2 Q. Okay.</p> <p>3 So comparing the work you did</p> <p>4 in the Niaspan case, and this case, the work</p> <p>5 that you've done so far -- let me back --</p> <p>6 let me strike that that question. Let me</p> <p>7 ask it a different way.</p> <p>8 The proposed methodology that</p> <p>9 you offered in the Niaspan case for</p> <p>10 identifying class members and the proposed</p> <p>11 methodology you have in this case, do those</p> <p>12 differ in any respect?</p> <p>13 MR. STANOCH: Objection to</p> <p>14 form.</p> <p>15 And again, I just caution the</p> <p>16 witness not to divulge information</p> <p>17 subject to a confidentiality order in a</p> <p>18 different case.</p> <p>19 Please proceed.</p> <p>20 A. Sure. It's a different -- it's</p> <p>21 a differently defined class in Niaspan. The</p> <p>22 data -- the very limited data that was</p> <p>23 produced in that case was different than the</p> <p>24 data that has been produced here and I</p> <p>25 believe that I am being particularly</p>	<p style="text-align: right;">Page 92</p> <p>1 L. Craft</p> <p>2 methodology for identifying TPPs and</p> <p>3 consumers different in the antitrust context</p> <p>4 than in a case involving the allegation made</p> <p>5 herein?</p> <p>6 MR. STANOCH: Objection to</p> <p>7 form.</p> <p>8 Vague.</p> <p>9 Ambiguous.</p> <p>10 Go ahead.</p> <p>11 A. It can be because the antitrust</p> <p>12 cases may involve changes in formulary</p> <p>13 status or, you know, questions about the</p> <p>14 difference between the plans, but for</p> <p>15 treatment of a generic when only the brand</p> <p>16 was in fact available. The issues were</p> <p>17 quite different.</p> <p>18 Q. How does that impact the</p> <p>19 identification of class members?</p> <p>20 MR. STANOCH: Objection.</p> <p>21 Incomplete hypothetical.</p> <p>22 Go ahead.</p> <p>23 A. It may raise additional issues</p> <p>24 that are addressed in the course of the</p> <p>25 case. Each case is different on its facts</p>
<p style="text-align: right;">Page 91</p> <p>1 L. Craft</p> <p>2 explicit here about how one would, if</p> <p>3 necessary, go about revolving the</p> <p>4 distinction between the ASO and insurer</p> <p>5 payors. So I would not describe them as the</p> <p>6 same.</p> <p>7 Q. Okay.</p> <p>8 Are those the only differences</p> <p>9 that you're aware of, the ones you just</p> <p>10 described?</p> <p>11 MR. STANOCH: Same objections.</p> <p>12 Go ahead.</p> <p>13 A. It's an entirely different case</p> <p>14 and it's a case that involved antitrust</p> <p>15 allegations with all of the issues that that</p> <p>16 implies, which are not relevant or germane</p> <p>17 to this litigation.</p> <p>18 In this case, we're only</p> <p>19 trying, from my perspective, to identify who</p> <p>20 paid for a specific, nicely delineated set</p> <p>21 of products by their NDC codes. We're just</p> <p>22 trying to identify those payors.</p> <p>23 Q. You referred to the fact that</p> <p>24 Niaspan was an antitrust case.</p> <p>25 Is the methodology for -- your</p>	<p style="text-align: right;">Page 93</p> <p>1 L. Craft</p> <p>2 and depending upon the specific allegations,</p> <p>3 so I can't generalize.</p> <p>4 Q. The court in the Niaspan case</p> <p>5 concluded that PBM data alone cannot readily</p> <p>6 identify fully insured plans. If that</p> <p>7 was -- let me pose it to you this way.</p> <p>8 If that was, in fact, the</p> <p>9 court's factual conclusion -- not legal,</p> <p>10 just factual -- is that factually accurate?</p> <p>11 MR. STANOCH: Objection to</p> <p>12 form.</p> <p>13 Vague.</p> <p>14 Ambiguous.</p> <p>15 Incomplete hypothetical.</p> <p>16 Unintelligible.</p> <p>17 Go ahead.</p> <p>18 A. First of all, let me say that</p> <p>19 it is not my position to label a federal</p> <p>20 judge's order as accurate or inaccurate and</p> <p>21 I am going to avoid any such</p> <p>22 characterization.</p> <p>23 I don't know what "readily"</p> <p>24 means in the quote that you just supplied.</p> <p>25 I don't know -- I know that there was only</p>

<p style="text-align: right;">Page 94</p> <p>1 L. Craft</p> <p>2 one limited sample of PBM data that was</p> <p>3 supplied in that case and that sample was</p> <p>4 missing a key relevant field, which is the</p> <p>5 group number, so it was pretty seriously</p> <p>6 incomplete.</p> <p>7 I would not suggest that when</p> <p>8 and if PBM data is gathered in this case</p> <p>9 that the PBM be allowed to withhold the</p> <p>10 group number. I would suggest that that be</p> <p>11 included as it routinely is, by the way, in</p> <p>12 many cases. So I'm not going to attempt to</p> <p>13 get into the judge's head and figure out</p> <p>14 what that sentence means, what the standard</p> <p>15 of "readily" is.</p> <p>16 I just told you that PBMs, I</p> <p>17 think, generally have payment status</p> <p>18 information and Mr. Kosty doesn't really</p> <p>19 challenge that except to say maybe they</p> <p>20 don't always and it's in a different</p> <p>21 database.</p> <p>22 The court addresses none of</p> <p>23 this in the Niaspan opinion and does not</p> <p>24 address the ability to obtain that same</p> <p>25 information from the ASOs and TPAs</p>	<p style="text-align: right;">Page 96</p> <p>1 L. Craft</p> <p>2 to go next.</p> <p>3 The other part of PBM data that</p> <p>4 I think you're referring to in your report</p> <p>5 in various places is the -- like the set up</p> <p>6 worksheets and the set up information that</p> <p>7 you were talking about earlier.</p> <p>8 Is that right?</p> <p>9 MR. STANOCH: Objection.</p> <p>10 A. No. There's lots more in the</p> <p>11 PBM claims data than what you just</p> <p>12 described. As I've now mentioned I think</p> <p>13 twice, it's not uncommon for a PBM to</p> <p>14 delineate in that claims data ASO or TPA.</p> <p>15 So you do see that delineation in claims</p> <p>16 data. It's just that you don't see it</p> <p>17 invariably in the claims data.</p> <p>18 So I am merely pointing out in</p> <p>19 this litigation that PBMs know their clients</p> <p>20 and, generally speaking, should be expected</p> <p>21 to be able to produce from their electronic</p> <p>22 data, but not within the claims data set,</p> <p>23 information about who the payor is, whether</p> <p>24 a particular plan is an ASO plan or is</p> <p>25 ASO -- I'm going to use the word ASO here</p>
<p style="text-align: right;">Page 95</p> <p>1 L. Craft</p> <p>2 themselves as to who the underlying payors</p> <p>3 are.</p> <p>4 Q. I'm going to unpack that a</p> <p>5 little bit, Ms. Craft. The first thing I</p> <p>6 want to clarify in your answer is just in</p> <p>7 terms of terminology. You identified</p> <p>8 "readily" as a concern, but I want to back</p> <p>9 up a few words.</p> <p>10 My question is to the phrase</p> <p>11 PBM data. PBM data, as I believe you</p> <p>12 understand it, is basically the NCPDP,</p> <p>13 things like plan ID, BIN, processor control</p> <p>14 number and group RX number.</p> <p>15 Is that -- that's part of it,</p> <p>16 right?</p> <p>17 MR. STANOCH: Objection.</p> <p>18 A. Those are elements -- I'm</p> <p>19 sorry.</p> <p>20 Q. Okay.</p> <p>21 A. Those are elements of PBM data.</p> <p>22 Certainly not all of them.</p> <p>23 Q. Okay.</p> <p>24 A. Data fields.</p> <p>25 Q. Right. And that's where I want</p>	<p style="text-align: right;">Page 97</p> <p>1 L. Craft</p> <p>2 just to make the communication clearer -- to</p> <p>3 encompass also TPA plans. It's an</p> <p>4 intermediary who has contracted with the</p> <p>5 PBM.</p> <p>6 I believe that the data is set</p> <p>7 up specifically to delineate those accounts</p> <p>8 separately so that they could be tracked by</p> <p>9 the ASO who receives the data and proper</p> <p>10 billing can be made to the clients. I don't</p> <p>11 mean to limit this to a question of plan set</p> <p>12 up sheets. I mean to say that the data is</p> <p>13 structured to enable that process to happen.</p> <p>14 Q. Okay.</p> <p>15 Let me back up then and I'm</p> <p>16 going to ask my question in a little bit</p> <p>17 different way.</p> <p>18 Using your description of PBM</p> <p>19 data and your understanding of PBM data that</p> <p>20 you just laid out for us, I'm going to take</p> <p>21 the word "readily" out of my question and</p> <p>22 ask it this way.</p> <p>23 If the court concluded in the</p> <p>24 Niaspan case that PBM data alone cannot</p> <p>25 identify fully insured plans, do you agree</p>

<p style="text-align: right;">Page 98</p> <p>1 L. Craft</p> <p>2 with that factual conclusion?</p> <p>3 MR. STANOCH: Objection to</p> <p>4 form.</p> <p>5 Asked and answered.</p> <p>6 Incomplete hypothetical.</p> <p>7 Calls for legal conclusion.</p> <p>8 I caution the witness not to</p> <p>9 divulge any information subject to a</p> <p>10 confidentiality order in a different</p> <p>11 case in rendering her answer here, but</p> <p>12 please proceed.</p> <p>13 A. Once again, I am loathe to take</p> <p>14 issue with a judge's conclusions because I</p> <p>15 don't know what facts inform them. I know</p> <p>16 that that particular decision was based on</p> <p>17 literally two examples and that is what the</p> <p>18 judge based his conclusion on, not something</p> <p>19 else, the two examples where group data was</p> <p>20 not supplied and the field formats suggested</p> <p>21 that these were fully insured prescription</p> <p>22 drug benefits.</p> <p>23 And years later, there was</p> <p>24 website content that suggested that health</p> <p>25 benefits generally for these two claimants</p>	<p style="text-align: right;">Page 100</p> <p>1 L. Craft</p> <p>2 decision, I cannot say.</p> <p>3 Q. In this case, there's no PBM</p> <p>4 data that's supplied whatsoever, is there?</p> <p>5 MR. STANOCH: Objection.</p> <p>6 A. Actually, I believe that one of</p> <p>7 the retailers effectively pulled from PBM</p> <p>8 data to be able to get the both mail order</p> <p>9 and retail claims, but what -- once again,</p> <p>10 I'm a little concerned about just calling it</p> <p>11 PBM data.</p> <p>12 The standard set of metrics</p> <p>13 that I would expect would be collected from</p> <p>14 PBMs in a case like this, as far as I know,</p> <p>15 has not been subpoenaed or collected at this</p> <p>16 point in the litigation.</p> <p>17 Q. Okay.</p> <p>18 Can we go to page -- let's do</p> <p>19 paragraph six on the next page of your</p> <p>20 report, please.</p> <p>21 A. Okay.</p> <p>22 Q. Just briefly I just want to</p> <p>23 discuss comp for a minute, Ms. Craft.</p> <p>24 You're being paid \$550 an hour</p> <p>25 for your services?</p>
<p style="text-align: right;">Page 99</p> <p>1 L. Craft</p> <p>2 literally comprising a handful of claims</p> <p>3 might have been at least four or five years</p> <p>4 later self-funded. I do not believe that</p> <p>5 that evidence suggests that PBM data cannot</p> <p>6 be used to adequately address the question</p> <p>7 of self-funding sponsor identification for</p> <p>8 ASO and TPA plans.</p> <p>9 So my opinion is that those</p> <p>10 facts which provide the narrow basis for the</p> <p>11 court's ruling, as I read it, are in no way</p> <p>12 dispositive or even particularly probative</p> <p>13 of the question of the adequacy of PBM data</p> <p>14 writ large.</p> <p>15 I just want to remind you that</p> <p>16 using the moniker PBM data is very</p> <p>17 confusing. The PBMs swim in an ocean of</p> <p>18 data. Their business is data. These are</p> <p>19 the people who generate reports that track</p> <p>20 individual human beings for ten years and</p> <p>21 say what drug did they obtain, which drug</p> <p>22 did they switch to. So there's lots and</p> <p>23 lots of PBM data and what it had in front of</p> <p>24 it there was a small sample that was missing</p> <p>25 fields. So how that influences the court's</p>	<p style="text-align: right;">Page 101</p> <p>1 L. Craft</p> <p>2 MR. STANOCH: Objection.</p> <p>3 A. No, I'm not. I'm not being</p> <p>4 paid -- I'm not being paid anything. On</p> <p>5 Point Analytics, my employer, is being paid</p> <p>6 \$550 an hour for my services.</p> <p>7 (Whereupon, Exhibit 6 was marked for</p> <p>8 identification.)</p> <p>9 Q. Okay. I appreciate the</p> <p>10 clarification.</p> <p>11 Let's go ahead and do exhibit</p> <p>12 pre-labeled F. This will be Exhibit 6.</p> <p>13 Ms. Craft, I don't intend to</p> <p>14 spend a lot of time poring through your</p> <p>15 invoices. I want to ask a couple questions</p> <p>16 about this.</p> <p>17 This is a collection of</p> <p>18 invoices that you or On Point has produced</p> <p>19 to us. On page one of the screen --</p> <p>20 actually, I take that back.</p> <p>21 Can we go all the way to page</p> <p>22 23 of this exhibit?</p> <p>23 A. Okay.</p> <p>24 Q. It should be 23 of the PDF,</p> <p>25 Ms. Craft. The exhibit shown on the screen</p>

<p style="text-align: right;">Page 102</p> <p>1 L. Craft</p> <p>2 is dated February 1, 2022 and it is for</p> <p>3 professional services through December 31,</p> <p>4 2021.</p> <p>5 Have you sent any additional</p> <p>6 invoices to plaintiff's counsel since</p> <p>7 February 1 -- I guess covering any periods</p> <p>8 post December 31, 2021?</p> <p>9 A. No.</p> <p>10 Q. Okay.</p> <p>11 Obviously there's been work</p> <p>12 done since December 31, 2021.</p> <p>13 Is that fair to say?</p> <p>14 A. Yes, but the January invoice</p> <p>15 has not yet been sent.</p> <p>16 Q. Okay. All right.</p> <p>17 Now, I went through these</p> <p>18 invoices and I'll just make some</p> <p>19 representations to you. All I'm looking for</p> <p>20 here is not an exact math calculation, but</p> <p>21 your sense as to whether or not it appears</p> <p>22 accurate based on my bad lawyer math.</p> <p>23 I went through it and it looks</p> <p>24 like I arrived at your having spent</p> <p>25 approximately 164 hours so far in this case.</p>	<p style="text-align: right;">Page 104</p> <p>1 L. Craft</p> <p>2 Is that consistent with your</p> <p>3 understanding of what's been received by On</p> <p>4 Point?</p> <p>5 MR. STANOCH: Same as prior</p> <p>6 objections.</p> <p>7 A. My understanding would be based</p> <p>8 upon review of these same documents that you</p> <p>9 are showing me. So I don't have any</p> <p>10 understanding independent of looking at</p> <p>11 these same documents and tallying up the</p> <p>12 payments, which I have not --</p> <p>13 Q. Does On Point -- sorry. I</p> <p>14 didn't mean to cut you off.</p> <p>15 Were you finished with your</p> <p>16 answer?</p> <p>17 A. Yes, I am. Thank you.</p> <p>18 Q. Of course.</p> <p>19 Has On Point worked with any of</p> <p>20 the plaintiff's counsel in this case before?</p> <p>21 Not getting into -- I don't want</p> <p>22 attorney-client information. I just want to</p> <p>23 know if you worked with them before.</p> <p>24 A. I've consulted on one other</p> <p>25 matter, but it's not one in which I'm</p>
<p style="text-align: right;">Page 103</p> <p>1 L. Craft</p> <p>2 Does that roughly match your</p> <p>3 recollection about how much time you've</p> <p>4 spent through December 31, 2021?</p> <p>5 MR. STANOCH: Objection to</p> <p>6 form.</p> <p>7 Documents speak for themselves.</p> <p>8 Go ahead.</p> <p>9 A. I have not summarized those</p> <p>10 numbers myself. That doesn't strike me as</p> <p>11 inherently wrong. The detail is accurately</p> <p>12 reported on each invoice where the time is</p> <p>13 broken out by timekeeper. So 160 hours</p> <p>14 doesn't strike me as wrong, but I'd have to</p> <p>15 replicate the math and add them up to see.</p> <p>16 Q. So you're saying we could do</p> <p>17 the same thing and get an accurate picture</p> <p>18 of what both you and your staff have spent</p> <p>19 on this case.</p> <p>20 Is that fair?</p> <p>21 A. That's correct.</p> <p>22 Q. Okay.</p> <p>23 Total collections I added up</p> <p>24 appear to be \$271,163.75 paid to On Point by</p> <p>25 plaintiff's counsel so far.</p>	<p style="text-align: right;">Page 105</p> <p>1 L. Craft</p> <p>2 identified as an expert.</p> <p>3 Q. Go to page 15 of Exhibit 6.</p> <p>4 Here, I am going to try to read just a small</p> <p>5 portion of this invoice.</p> <p>6 In the top entry, a person</p> <p>7 designated as CW -- who I understand to be a</p> <p>8 Mr. or Ms. Wallace -- let me stop there.</p> <p>9 Do you know who I'm talking</p> <p>10 about?</p> <p>11 A. Yes, that abbreviation stands</p> <p>12 for Chandra Wallace.</p> <p>13 Q. So Ms. Wallace then?</p> <p>14 A. Yes, correct.</p> <p>15 Q. So Ms. Wallace here indicates</p> <p>16 she researched and reviewed six segmented</p> <p>17 orders on motions to dismiss and then below</p> <p>18 that appears to have done that again the</p> <p>19 next day on September 9th, 2021 where she</p> <p>20 completed review of recent motions.</p> <p>21 My question to you is this:</p> <p>22 What was the purpose of her review of the</p> <p>23 motions to dismiss?</p> <p>24 A. Well, what you see is, first of</p> <p>25 all, that the top entry, September 8, refers</p>

<p style="text-align: right;">Page 106</p> <p>1 L. Craft</p> <p>2 to the orders. The second entry on</p> <p>3 September 9 refers to motions and I don't</p> <p>4 know that those are the same motions. It</p> <p>5 refers to motions.</p> <p>6 Q. The next word is orders.</p> <p>7 Let me clarify that. The next</p> <p>8 word is orders, so I guess I should have</p> <p>9 drawn your attention there as well.</p> <p>10 I'm referring specifically to</p> <p>11 the orders on the motion to dismiss. I</p> <p>12 apologize.</p> <p>13 MR. STANOCH: Mr. Dorner, I'm</p> <p>14 not accusing you, but just let her</p> <p>15 answer. Thanks.</p> <p>16 MR. DORNER: No problem.</p> <p>17 Go ahead and continue.</p> <p>18 A. The September 9 entry I'm just</p> <p>19 noting doesn't say anything specifically</p> <p>20 about motions to dismiss. You are drawing</p> <p>21 the inference.</p> <p>22 When you say she did the same</p> <p>23 thing again on September 9, I don't think</p> <p>24 you could draw that inference from this.</p> <p>25 The September 9 entry merely says "Complete</p>	<p style="text-align: right;">Page 108</p> <p>1 L. Craft</p> <p>2 Q. In forming your opinions, have</p> <p>3 any of the substantive opinions in the</p> <p>4 motions to dismiss expressed by Judge Kugler</p> <p>5 -- let me strike this and reword it because</p> <p>6 it's a horrible question. Let me try that</p> <p>7 again.</p> <p>8 In forming the opinions</p> <p>9 expressed in your reports, have you relied</p> <p>10 upon any of the Court's decisions on the</p> <p>11 defendants' motions to dismiss referenced in</p> <p>12 this invoice?</p> <p>13 MR. STANOCH: Objection to</p> <p>14 form.</p> <p>15 Go ahead.</p> <p>16 A. No, I have not.</p> <p>17 MR. DORNER: So I know I -- I</p> <p>18 think I'm at about an hour right now</p> <p>19 and I'm sort of at a point where I can</p> <p>20 transition and also I'd like to use the</p> <p>21 restroom. So if we don't mind taking a</p> <p>22 quick five minutes, I'd appreciate</p> <p>23 that.</p> <p>24 Is that okay?</p> <p>25 THE WITNESS: Okay.</p>
<p style="text-align: right;">Page 107</p> <p>1 L. Craft</p> <p>2 review of recent motions and orders."</p> <p>3 You're correct in highlighting now that</p> <p>4 latter word.</p> <p>5 In general, although we're not</p> <p>6 in the business of lawyering or thinking</p> <p>7 about legal strategy, we stay pretty tightly</p> <p>8 focused on the areas of expertise that are</p> <p>9 expressed in our opinions. That doesn't</p> <p>10 mean that we don't try to procedurally keep</p> <p>11 track of what's going on in a case. So it's</p> <p>12 not unusual in our firm for there to be a</p> <p>13 docket review that is periodically</p> <p>14 undertaken just involving pulling up from</p> <p>15 the actual docket for a case using Case</p> <p>16 Central and -- to just see what's going on.</p> <p>17 Just to make sure we don't have any</p> <p>18 surprises. For example, the schedule has</p> <p>19 changed and these counsel are fantastic, but</p> <p>20 it does occasionally happen that some</p> <p>21 lawyers don't keep us in the loop and we</p> <p>22 find it's a good idea to just keep an eye on</p> <p>23 the docket for our own purposes.</p> <p>24 So beyond that, I can't comment</p> <p>25 further.</p>	<p style="text-align: right;">Page 109</p> <p>1 L. Craft</p> <p>2 MR. DORNER: I'll see you back</p> <p>3 here at 10:19 Pacific.</p> <p>4 THE VIDEOGRAPHER: Time is</p> <p>5 10:13.</p> <p>6 This ends media unit two.</p> <p>7 We're going off the record.</p> <p>8 (Recess taken)</p> <p>9 THE VIDEOGRAPHER: The time is</p> <p>10 10:23.</p> <p>11 This begins media unit three.</p> <p>12 We're back on the record.</p> <p>13 MR. DORNER: Welcome back</p> <p>14 everybody. Ms. Craft -- tell you</p> <p>15 what -- Justin, let's pull up Exhibit</p> <p>16 4, go to page six, paragraph eight.</p> <p>17 Q. Really, before I even get to</p> <p>18 questions about paragraphs eight and nine, I</p> <p>19 wanted to ask you, Ms. Craft, for purposes</p> <p>20 of identifying who class members would be,</p> <p>21 would you agree it's immaterial whether the</p> <p>22 valsartan that a consumer purchased was</p> <p>23 actually recalled to your identification</p> <p>24 methodology?</p> <p>25 MR. STANOCH: Objection to</p>

<p style="text-align: right;">Page 110</p> <p>1 L. Craft</p> <p>2 form.</p> <p>3 Vague.</p> <p>4 Go ahead.</p> <p>5 A. Yes. The recall status of the</p> <p>6 product is not a factor that I've taken into</p> <p>7 consideration.</p> <p>8 Q. Why is that?</p> <p>9 A. It's my understanding that some</p> <p>10 of the product challenged in this case was</p> <p>11 manufactured prior to the time that the</p> <p>12 defendants initiated their recalls and some</p> <p>13 of that product was expired, was no longer</p> <p>14 being sold and so obviously whatever harm</p> <p>15 those products may have caused due to</p> <p>16 nitrosamine contamination was already -- had</p> <p>17 already occurred prior to any recalls being</p> <p>18 initiated.</p> <p>19 So I don't think -- I did not</p> <p>20 read the fact of a defendant recall as being</p> <p>21 the dispositive indication that a product</p> <p>22 was or was not contaminated.</p> <p>23 Q. And actually that's -- let me</p> <p>24 jump off that answer.</p> <p>25 Whether or not a particular</p>	<p style="text-align: right;">Page 112</p> <p>1 L. Craft</p> <p>2 Did I attempt to make any</p> <p>3 distinction between recalls and recalled</p> <p>4 products in my report? I did not.</p> <p>5 Q. I want to focus on NDCs that</p> <p>6 you just brought up in paragraph -- let's</p> <p>7 close this call out. I think I meant</p> <p>8 paragraph nine. I apologize.</p> <p>9 So here you've got a statement</p> <p>10 that the -- I believe it's down near the</p> <p>11 bottom -- the NDC is universally used to</p> <p>12 identify the product at each step in the</p> <p>13 distribution process, including in the final</p> <p>14 sale to consumers.</p> <p>15 When you say NDCs are used to</p> <p>16 identify a product, first of all, you'd</p> <p>17 agree that the term "product" isn't</p> <p>18 referring to a specific bottle of a</p> <p>19 medication, right?</p> <p>20 MR. STANOCH: Objection.</p> <p>21 Q. Let me ask this a different</p> <p>22 way.</p> <p>23 When you say product and you</p> <p>24 refer to a product and an NDC used to</p> <p>25 identify the product, an NDC code can't be</p>
<p style="text-align: right;">Page 111</p> <p>1 L. Craft</p> <p>2 valsartan-containing drug that a consumer or</p> <p>3 a TPP paid for, whether it actually even</p> <p>4 contained NDMA or NDEA is also not pertinent</p> <p>5 to your identification methodology; is that</p> <p>6 also correct?</p> <p>7 MR. STANOCH: Objection to</p> <p>8 form.</p> <p>9 Misstates opinions.</p> <p>10 Go ahead.</p> <p>11 A. It's not pertinent in the sense</p> <p>12 that I didn't attempt to investigate the</p> <p>13 contamination -- presence or absence of</p> <p>14 contamination for particular products. It</p> <p>15 is pertinent in the sense that if one were</p> <p>16 to determine that a particular NDC product</p> <p>17 was not contaminated, that could be removed</p> <p>18 from the challenged products very readily</p> <p>19 using the data I have identified because all</p> <p>20 of the data sources that I discuss in my</p> <p>21 report are NDC specific. So particular NDCs</p> <p>22 could be removed if it were later determined</p> <p>23 they were not contaminated and I think</p> <p>24 that's a -- that's an important fact to be</p> <p>25 aware of.</p>	<p style="text-align: right;">Page 113</p> <p>1 L. Craft</p> <p>2 used to pick out an individual bottle of a</p> <p>3 medication from any other bottle of a</p> <p>4 medication that also has the same NDC.</p> <p>5 Fair?</p> <p>6 A. The NDCs does not distinguish</p> <p>7 between bottles of medication that has the</p> <p>8 same NDC. It's axiomatic that if the NDC on</p> <p>9 those two bottles is the same, it's the same</p> <p>10 product. That's -- we refer to these as</p> <p>11 drug products in the pharmaceutical industry</p> <p>12 and a drug product is being defined by its</p> <p>13 chemical composition, its strength, its</p> <p>14 formulation. Those are common elements that</p> <p>15 link back to the manufacturer of the product</p> <p>16 and then one step further, back to an IP</p> <p>17 supplier. That's what's getting captured as</p> <p>18 the common characteristics, using the NDC.</p> <p>19 Q. Okay.</p> <p>20 And then an NDC also doesn't</p> <p>21 identify a specific -- again, let me</p> <p>22 rephrase this question before I know what</p> <p>23 happens.</p> <p>24 An NDC can include -- would</p> <p>25 include all lots or batches of any given</p>

<p style="text-align: right;">Page 114</p> <p>1 L. Craft</p> <p>2 drug product, correct?</p> <p>3 MR. STANOCH: Objection to</p> <p>4 form.</p> <p>5 You may answer.</p> <p>6 A. Yes. A lot is a further</p> <p>7 subdivision of an NDC.</p> <p>8 Q. Can we go to paragraph ten,</p> <p>9 please, on page seven?</p> <p>10 I want to focus your attention,</p> <p>11 Ms. Craft, on the phrase -- it's in the</p> <p>12 middle of the paragraph -- "Multiple parties</p> <p>13 exchange, record and maintain the</p> <p>14 transaction-specific data for virtually all</p> <p>15 insured prescriptions dispensed in this</p> <p>16 country, including the identity of both the</p> <p>17 patient, their health plan and the exact</p> <p>18 amounts paid by each."</p> <p>19 When you use the term "exact</p> <p>20 amounts," that phrase would not take into</p> <p>21 account any post-sale adjustments to the</p> <p>22 consumer or the health plan's net cost,</p> <p>23 would it?</p> <p>24 MR. STANOCH: Objection to the</p> <p>25 form.</p>	<p style="text-align: right;">Page 116</p> <p>1 L. Craft</p> <p>2 A. Nope. That's not right. So</p> <p>3 first of all, refunds and credits are</p> <p>4 frequently reported in the PBM data and in</p> <p>5 TPP data because they are part of the</p> <p>6 payment record for individual transactions.</p> <p>7 So in a given PBM with claims data, you</p> <p>8 might expect to see something approaching</p> <p>9 20% of transactions as either canceled or</p> <p>10 reversed. Typically, those are returns to</p> <p>11 stock based --</p> <p>12 Q. Ms. Craft, you froze.</p> <p>13 A. Oh, dear. Okay.</p> <p>14 Q. Ms. Craft, I may be able to</p> <p>15 help you. I have sort of a realtime here.</p> <p>16 You had said --</p> <p>17 MR. HONIK: No, no, no. Let</p> <p>18 the court reporter read back what she</p> <p>19 has and the witness can pick up from</p> <p>20 there.</p> <p>21 THE WITNESS: Yes. And please</p> <p>22 let me know if that happens again.</p> <p>23 That's very unusual here in the office.</p> <p>24 MR. DORNER: Dave, was that you</p> <p>25 speaking?</p>
<p style="text-align: right;">Page 115</p> <p>1 L. Craft</p> <p>2 Vague.</p> <p>3 Ambiguous.</p> <p>4 Go ahead.</p> <p>5 A. I don't believe that post-sale</p> <p>6 adjustments are, number one, specific to</p> <p>7 individual purchases of an individual drug,</p> <p>8 nor do I believe that they are germane to</p> <p>9 the question of what was paid and by whom at</p> <p>10 the point of sale, which I believe to be the</p> <p>11 focus of this inquiry. But I wish to</p> <p>12 underscore that first point because I think</p> <p>13 it has been very misleadingly described by</p> <p>14 Mr. Kosty.</p> <p>15 Q. So I guess let me ask again.</p> <p>16 The types of</p> <p>17 transaction-specific data that you proposed</p> <p>18 to use in this case would not reflect</p> <p>19 post-sale adjustments, refunds, credits,</p> <p>20 anything of that nature? It solely focused</p> <p>21 on the point of sale; is that right?</p> <p>22 MR. STANOCH: Objection to</p> <p>23 form.</p> <p>24 Asked and answered.</p> <p>25 Vague.</p>	<p style="text-align: right;">Page 117</p> <p>1 L. Craft</p> <p>2 MR. STANOCH: That was Ruben</p> <p>3 Honik.</p> <p>4 MR. DORNER: Okay.</p> <p>5 Well, if you're going to be</p> <p>6 objecting on behalf of your witness,</p> <p>7 you're supposed to be on video.</p> <p>8 MR. HONIK: I'm not objecting.</p> <p>9 I'm only pointing out the obvious.</p> <p>10 You're not the court reporter. Let the</p> <p>11 court reporter read what she has thus</p> <p>12 far and the witness can pick up from</p> <p>13 there. That's all.</p> <p>14 THE WITNESS: That would be</p> <p>15 helpful. Thank you.</p> <p>16 (Whereupon, the record was read</p> <p>17 back by the reporter.)</p> <p>18 A. -- on the consumer failing to</p> <p>19 pick up the prescription. These are easily</p> <p>20 identifiable in the data, typically with the</p> <p>21 symbols R and X, returns and cancellations.</p> <p>22 So I would agree with your</p> <p>23 description of returns and credits; however,</p> <p>24 I believe what you are referring to are</p> <p>25 surrogate payment adjustments across entire</p>

<p style="text-align: right;">Page 118</p> <p>1 L. Craft</p> <p>2 portfolios of drugs that may be embedded in</p> <p>3 some pharmacy contracts that, in my opinion,</p> <p>4 are utterly and completely irrelevant to</p> <p>5 what was paid for valsartan-containing</p> <p>6 drugs.</p> <p>7 Those accounting adjustments to</p> <p>8 entire books of business are not drug</p> <p>9 specific. They do not change in any way --</p> <p>10 the phrase you used was "net price" that was</p> <p>11 paid for the valsartan-containing drug.</p> <p>12 Q. I was actually referring to the</p> <p>13 other -- to the sort of refund or credit, as</p> <p>14 we might use it in common terminology.</p> <p>15 If, for example, a consumer</p> <p>16 were to be given a refund or a credit for a</p> <p>17 prescription, are you saying that would be</p> <p>18 reflected in the transaction-specific data</p> <p>19 that you would obtain in this case?</p> <p>20 MR. STANOCH: Objection to</p> <p>21 form.</p> <p>22 Misstates the testimony.</p> <p>23 Incomplete hypothetical.</p> <p>24 Compound.</p> <p>25 Ambiguous.</p>	<p style="text-align: right;">Page 120</p> <p>1 L. Craft</p> <p>2 to have a record of refunds paid. You don't</p> <p>3 send people money without keeping a record</p> <p>4 of who you sent it to.</p> <p>5 Q. Now, I don't believe your</p> <p>6 report provides for any methodology for</p> <p>7 applying refunds that were paid either to</p> <p>8 TPPs or to consumers for purposes of</p> <p>9 identifying the class.</p> <p>10 That's true, right?</p> <p>11 MR. STANOCH: Objection to</p> <p>12 form.</p> <p>13 Vague.</p> <p>14 Ambiguous.</p> <p>15 Compound.</p> <p>16 Go ahead.</p> <p>17 A. I don't recall having discussed</p> <p>18 the refund process in my report, nor do I</p> <p>19 know whether it was -- the amount of refunds</p> <p>20 paid were, in fact, material in this case.</p> <p>21 So I don't have an opinion</p> <p>22 about that, but I do know that these are --</p> <p>23 if, for example, the PBM is linked to a</p> <p>24 pharmacy and the pharmacy is paying out a</p> <p>25 refund, that may appear in the PBM record.</p>
<p style="text-align: right;">Page 119</p> <p>1 L. Craft</p> <p>2 Go ahead, if you can.</p> <p>3 A. So are you asking in your</p> <p>4 questions specifically about product returns</p> <p>5 related to recalls?</p> <p>6 Q. Well, let's treat it like that.</p> <p>7 Sure.</p> <p>8 A. Okay.</p> <p>9 MR. STANOCH: Same objections.</p> <p>10 Go ahead.</p> <p>11 A. Yes. Because it depends on</p> <p>12 what kind of refund or credit you're talking</p> <p>13 about here. So if what you are discussing</p> <p>14 is the return of product that has been</p> <p>15 recalled and whether that particular -- that</p> <p>16 generates a refund to the consumer, the --</p> <p>17 in general, the records of such returns will</p> <p>18 be maintained by the manufacturer that has</p> <p>19 initiated the recall and that is paying the</p> <p>20 refund or the entity that it has designated</p> <p>21 to handle its recall effort on its behalf.</p> <p>22 So an entity, that may be the</p> <p>23 manufacturer, it may be its wholesaler, it</p> <p>24 may be a specifically designated entity to</p> <p>25 do recall management. That entity is going</p>	<p style="text-align: right;">Page 121</p> <p>1 L. Craft</p> <p>2 But there will be a master record of refunds</p> <p>3 that will be electronically available</p> <p>4 depending on who is handling the recall.</p> <p>5 I was not -- I was not asked to</p> <p>6 opine on returns triggered by the recall,</p> <p>7 but they are, of course, electronically</p> <p>8 documented.</p> <p>9 Q. So in order to identify a class</p> <p>10 member, isn't it essential -- well, let me</p> <p>11 back up.</p> <p>12 In order to identify anybody</p> <p>13 who, to use the class definition, paid money</p> <p>14 for valsartan-containing drugs, don't you</p> <p>15 have to know whether or not they got a</p> <p>16 refund or a credit?</p> <p>17 MR. STANOCH: Objection to</p> <p>18 form.</p> <p>19 Vague.</p> <p>20 Ambiguous.</p> <p>21 Incomplete hypothetical.</p> <p>22 Go ahead.</p> <p>23 A. Well, you are asking me a legal</p> <p>24 question about what you'd have to know,</p> <p>25 which implies what's the standard. Is it,</p>

<p style="text-align: right;">Page 122</p> <p>1 L. Craft</p> <p>2 in fact, legally necessary to determine in</p> <p>3 advance that someone was not fully refunded,</p> <p>4 that a given consumer was not fully refunded</p> <p>5 their purchase price?</p> <p>6 This is the kind of thing that</p> <p>7 one would ordinarily expect to see on a</p> <p>8 claim form. When you say I bought this</p> <p>9 product, yes, I did, and I paid for it, one</p> <p>10 could easily see and I did not receive a</p> <p>11 refund of this -- of these payments.</p> <p>12 So whether it's necessary when</p> <p>13 you say don't you have to, I think the</p> <p>14 answer is no.</p> <p>15 Q. So your methodology then for</p> <p>16 identifying class members is not going to</p> <p>17 take into account whether or not the class</p> <p>18 member received a refund or credit in</p> <p>19 association with recalled valsartan?</p> <p>20 MR. STANOCH: Objection to</p> <p>21 form.</p> <p>22 Asked and answered.</p> <p>23 Misstates testimony.</p> <p>24 Vague.</p> <p>25 Ambiguous.</p>	<p style="text-align: right;">Page 124</p> <p>1 L. Craft</p> <p>2 on your use of IQVIA -- that's I-Q-V-I-A --</p> <p>3 data.</p> <p>4 The IQVIA data you're referring</p> <p>5 to in paragraph 12 would be the Xponent.</p> <p>6 And for the benefit of the</p> <p>7 court reporter, that's the word exponent,</p> <p>8 but with an E at the beginning.</p> <p>9 Is that right?</p> <p>10 A. That's correct.</p> <p>11 Q. You used Xponent data for</p> <p>12 forming some of your opinions in this case,</p> <p>13 right?</p> <p>14 A. I used them for the purpose of</p> <p>15 forming the numerosity opinion.</p> <p>16 Q. Has IQVIA imposed any</p> <p>17 limitations, to your knowledge, on the use</p> <p>18 of its Xponent data for use of litigation</p> <p>19 purposes?</p> <p>20 MR. STANOCH: Objection to</p> <p>21 form.</p> <p>22 A. Do you mean in this case?</p> <p>23 Q. I mean at all.</p> <p>24 MR. STANOCH: Objection.</p> <p>25 Vague.</p>
<p style="text-align: right;">Page 123</p> <p>1 L. Craft</p> <p>2 Incomplete hypothetical.</p> <p>3 Go ahead.</p> <p>4 A. If the method of refunds</p> <p>5 records were -- it certainly would. Whether</p> <p>6 that was a step that was necessary, given</p> <p>7 that claim filing could include a statement</p> <p>8 along the lines that I've suggested and that</p> <p>9 if it were determined to be necessary,</p> <p>10 refunds could be used to offset damage</p> <p>11 numbers on an aggregate basis for the entire</p> <p>12 class.</p> <p>13 I'm not at all aware of</p> <p>14 circumstances that would make it necessary</p> <p>15 to link each refunds that was, in fact, paid</p> <p>16 to an individual consumer.</p> <p>17 Q. Okay.</p> <p>18 In your report, as you said, I</p> <p>19 don't think it discusses application of</p> <p>20 refund data in any respect, correct?</p> <p>21 MR. STANOCH: Asked and</p> <p>22 answered.</p> <p>23 A. Yeah, I think that's correct.</p> <p>24 Q. Let's go to page eight of your</p> <p>25 report, paragraph 12. I want to focus here</p>	<p style="text-align: right;">Page 125</p> <p>1 L. Craft</p> <p>2 Ambiguous.</p> <p>3 Unintelligible.</p> <p>4 A. Every IQVIA purchase comes with</p> <p>5 a license agreement that specifies the</p> <p>6 permitted uses of the data. That is</p> <p>7 routinely the case. I do not know what the</p> <p>8 license agreement says in this case.</p> <p>9 Q. Did you look into it?</p> <p>10 A. No. I use this data every day</p> <p>11 of the week in a variety of cases. So no.</p> <p>12 I have no reason to question whether it was</p> <p>13 properly obtained and is being properly used</p> <p>14 here.</p> <p>15 Q. Now, Xponent data like the kind</p> <p>16 you used are aggregated to the monthly level</p> <p>17 for each plan that is discussed in the data.</p> <p>18 Is that right?</p> <p>19 A. Yes, but you failed to add the</p> <p>20 other critical element, which is that they</p> <p>21 are separated by NDC. So each product plan</p> <p>22 and month and further, the state -- so we</p> <p>23 have four variables there that are</p> <p>24 accounting for each observation. So it is</p> <p>25 aggregate data, but it's not terribly</p>

<p style="text-align: right;">Page 126</p> <p>1 L. Craft</p> <p>2 aggregate. You're getting purchases of a</p> <p>3 single NDC in a single state by an</p> <p>4 identified plan over a single month. So</p> <p>5 that's the level of aggregation of the</p> <p>6 Xponent data.</p> <p>7 Q. Then it doesn't go down to the</p> <p>8 consumer level, right?</p> <p>9 A. It does not. Consumers who pay</p> <p>10 cash for their products are treated as cash</p> <p>11 payors and so the number of prescriptions</p> <p>12 filled in a given month for cash payors is</p> <p>13 reported for each NDC.</p> <p>14 There is additional data</p> <p>15 available from Xponent. I don't know</p> <p>16 whether it was obtained in -- sorry, from</p> <p>17 IQVIA -- which is called co-pay data, which</p> <p>18 does go down to the consumer level and</p> <p>19 report individual payments by consumers for</p> <p>20 individual transaction fills.</p> <p>21 Q. I believe that to the extent</p> <p>22 IQVIA has gaps in their data, they'll use</p> <p>23 projections to fill out the rest of their</p> <p>24 data.</p> <p>25 Isn't that right?</p>	<p style="text-align: right;">Page 128</p> <p>1 L. Craft</p> <p>2 Just for purposes of this</p> <p>3 deposition, I just want to make sure we're</p> <p>4 on the same page.</p> <p>5 When I say TPP, I'm referring</p> <p>6 to the proposed TPP class member that would</p> <p>7 ultimately be responsible for paying the</p> <p>8 claim.</p> <p>9 Is that -- we're on the same</p> <p>10 page there?</p> <p>11 A. Yes. I'm using this to mean</p> <p>12 third-party payer, yes.</p> <p>13 Q. Okay. Great. And that could</p> <p>14 be as opposed to a payor without the first T</p> <p>15 and P before it, a payor might be some other</p> <p>16 entity but isn't necessarily a TPP.</p> <p>17 Fair enough?</p> <p>18 A. That's precisely the ASO/TPA</p> <p>19 issue that we were discussing earlier this</p> <p>20 morning. There is the possibility for the</p> <p>21 payor that is contracting with the PBM to be</p> <p>22 acting in a representative capacity for the</p> <p>23 TPP.</p> <p>24 Q. Okay.</p> <p>25 I think I just want to ask a</p>
<p style="text-align: right;">Page 127</p> <p>1 L. Craft</p> <p>2 A. Yes. There is some projection.</p> <p>3 It's less than 100% of transactions are</p> <p>4 actually observed and IQVIA has an extremely</p> <p>5 sophisticated methodology for projecting the</p> <p>6 balance and assigning that balance to</p> <p>7 particular classes of payors, locations and</p> <p>8 NDCs on a monthly basis and it is the</p> <p>9 standard comprehensive reporting database</p> <p>10 relied upon almost universally by all</p> <p>11 participants in the pharmaceutical industry</p> <p>12 in the United States as an enumeration of</p> <p>13 all filled transactions or filled</p> <p>14 prescriptions, whether retail or</p> <p>15 wholesale -- sorry -- retail or mail order.</p> <p>16 Q. Let's go ahead and move on to</p> <p>17 page 12 of your report. This is paragraph</p> <p>18 20.</p> <p>19 I apologize for the delay</p> <p>20 there, Ms. Craft.</p> <p>21 Just as a point of</p> <p>22 clarification, here in paragraph 20, we see</p> <p>23 the term TPPs. I'm sure it appears earlier</p> <p>24 in your report, but this is the first</p> <p>25 occasion I have to bring it up.</p>	<p style="text-align: right;">Page 129</p> <p>1 L. Craft</p> <p>2 couple of questions to put some meat on the</p> <p>3 bone here about that specific scenario.</p> <p>4 So TPPs don't uniformly</p> <p>5 contract with pharmacy benefit managers or</p> <p>6 PBMs for claims adjudication, right?</p> <p>7 MR. STANOCH: Objection to</p> <p>8 form.</p> <p>9 Go ahead.</p> <p>10 A. I don't know what you mean by</p> <p>11 uniformly. If you mean -- if you mean</p> <p>12 invariably, I would agree with you.</p> <p>13 Q. And I did. That's what I</p> <p>14 meant.</p> <p>15 One of the -- I think maybe we</p> <p>16 could -- earlier in the deposition you had</p> <p>17 said we'll use the term ASO to include both</p> <p>18 administrative services only and third-party</p> <p>19 administrators.</p> <p>20 A. Mm-hmm.</p> <p>21 Q. So sometimes these TPPs will,</p> <p>22 in fact, be under contract not with the PBM,</p> <p>23 but rather the ASO for the claims</p> <p>24 adjudication services, right?</p> <p>25 A. Yes, but let's be clear that</p>

<p style="text-align: right;">Page 130</p> <p>1 L. Craft</p> <p>2 the actions that the ASO then takes in</p> <p>3 contracting with the PBM are on behalf of</p> <p>4 the TPP. The ASO is doing nothing, but</p> <p>5 securing that service for them. They are</p> <p>6 operating in a representative capacity.</p> <p>7 Q. Now, sometimes it's possible</p> <p>8 that instead of contracting directly with a</p> <p>9 third party -- excuse me. Let me back up.</p> <p>10 Sometimes it's possible that</p> <p>11 rather than be under contract with a</p> <p>12 pharmacy benefits manager directly, an ASO</p> <p>13 might contract with a second ASO or TPA who</p> <p>14 then contracts with the PBM, right?</p> <p>15 MR. STANOCH: Objection to</p> <p>16 form.</p> <p>17 A. I believe your hypothetical is</p> <p>18 is it possible for an ASO to contract with a</p> <p>19 second ASO, which then contracts with a PBM?</p> <p>20 Is that the question you're</p> <p>21 asking?</p> <p>22 Q. Yes.</p> <p>23 A. I would say that's extremely</p> <p>24 rare if it occurs.</p> <p>25 Q. It does occur, though?</p>	<p style="text-align: right;">Page 132</p> <p>1 L. Craft</p> <p>2 which generate this electronic record that</p> <p>3 is used in billing and collection and</p> <p>4 auditing individual claims.</p> <p>5 So I think we see this in the</p> <p>6 sense TPPs hire PBMs to perform a wide array</p> <p>7 of services for them. The same is true for</p> <p>8 ASOs. So you can't say just because there's</p> <p>9 a benefit administrator involve in the mix</p> <p>10 that that has somehow interrupted the</p> <p>11 connection between the TPP and the PBM's</p> <p>12 claims adjudication data.</p> <p>13 Q. I think I see what you're</p> <p>14 saying. So really, if you wanted to figure</p> <p>15 out what the intermediary -- the ASO -- was</p> <p>16 doing, you'd have to actually look at the</p> <p>17 relationship between the ASO and either the</p> <p>18 TPP or the other ASO that it's contracted</p> <p>19 with, right?</p> <p>20 MR. STANOCH: Objection to</p> <p>21 form.</p> <p>22 Vague.</p> <p>23 Ambiguous.</p> <p>24 Go ahead.</p> <p>25 A. Absolutely not. Absolutely</p>
<p style="text-align: right;">Page 131</p> <p>1 L. Craft</p> <p>2 A. I can't -- no, I'm not going to</p> <p>3 confirm that it occurs. I'm saying it's not</p> <p>4 theoretically impossible for it to occur.</p> <p>5 I'm saying it's not -- it should not be</p> <p>6 considered a significant issue.</p> <p>7 Q. And why shouldn't it be</p> <p>8 considered a significant issue?</p> <p>9 A. Because as I just said, that</p> <p>10 would be extremely rare. And let's be very</p> <p>11 clear here, there are all kinds of services</p> <p>12 that I believe were referenced in the</p> <p>13 earlier paragraph we were looking at and so</p> <p>14 when we get into loose talk about TPAs and</p> <p>15 PBMs -- and hopefully we'll get an</p> <p>16 opportunity to discuss Mr. Kosty's reliance</p> <p>17 on the PBMI surveys, which conflate these</p> <p>18 issues -- it's possible to have a benefit</p> <p>19 administrator who is really there to help</p> <p>20 design the plan and who is there to</p> <p>21 advise -- maybe to do customer service or a</p> <p>22 variety of other things.</p> <p>23 What we're concerned about here</p> <p>24 with regard to ascertainability is the</p> <p>25 procurement of claims adjudication services</p>	<p style="text-align: right;">Page 133</p> <p>1 L. Craft</p> <p>2 not. You do not need to look at all of</p> <p>3 those relationships. On the contrary, what</p> <p>4 I'm talking about is a programmatic</p> <p>5 data-driven exercise that identifies the</p> <p>6 client account and group and then links that</p> <p>7 to the entity that contracted with the PBM</p> <p>8 and then says if that entity is not the</p> <p>9 ultimate payor, the TPP, who then is that</p> <p>10 entity's client on behalf of whom is acting.</p> <p>11 I'm not suggesting that you</p> <p>12 need to do any inquiry into the nature of</p> <p>13 services, the numbers of intermediaries. I</p> <p>14 think that's a complete red herring.</p> <p>15 Q. I think you used the word</p> <p>16 "programmatic" in your last response.</p> <p>17 What do you define as</p> <p>18 programmatic?</p> <p>19 A. Something that is executed</p> <p>20 through software programming.</p> <p>21 Q. Can we go to paragraph 27,</p> <p>22 which is on page 16, please? There we go.</p> <p>23 I want to focus on the first</p> <p>24 sentence, specifically your reference to</p> <p>25 additional fields about the payor that</p>

<p style="text-align: right;">Page 134</p> <p>1 L. Craft</p> <p>2 appear automatically when the incoming</p> <p>3 pharmacy message is instantly linked to</p> <p>4 information collected and maintained by</p> <p>5 PBMs.</p> <p>6 I'm going to stop reading</p> <p>7 there, but the sentence continues.</p> <p>8 When you used the term "payor"</p> <p>9 here, payor can mean any entity? It could</p> <p>10 be a TPP or an ASO or a third-party</p> <p>11 administrator or another PBM, right?</p> <p>12 MR. STANOCH: Objection.</p> <p>13 A. Specifically, I'm referring --</p> <p>14 when I say about the payor, I'm referring to</p> <p>15 the entity who has the contractual</p> <p>16 relationship with the PBM and will be</p> <p>17 required to pay money to the PBM, whether it</p> <p>18 is acting as an ASO or whether it is acting</p> <p>19 as the ultimate payor on a self-funded</p> <p>20 employment plan or union plan.</p> <p>21 Q. So when we're talking about</p> <p>22 this NCPDP set of information in these NCPDP</p> <p>23 fields and linking to information maintained</p> <p>24 by the PBMs about the payor, from the PBM's</p> <p>25 perspective, the PBM just wants to get paid</p>	<p style="text-align: right;">Page 136</p> <p>1 L. Craft</p> <p>2 MR. STANOCH: Objection to</p> <p>3 form.</p> <p>4 A. That is one purpose for the</p> <p>5 specific fields.</p> <p>6 Q. I want to refer specifically --</p> <p>7 sorry, were you finished?</p> <p>8 A. Yes, I am. Thank you.</p> <p>9 Q. My pleasure.</p> <p>10 Let's drop this call out and</p> <p>11 just look up a little higher on page 15. I</p> <p>12 want to focus on the second column of that</p> <p>13 diagram, the one with the little building in</p> <p>14 it.</p> <p>15 So those fields of NCPDP data,</p> <p>16 as well as the additional data that you</p> <p>17 refer to in paragraph 27, considering only</p> <p>18 those two things, the purpose of that</p> <p>19 information is to ensure that the claim is</p> <p>20 routed to the proper -- excuse me -- first</p> <p>21 from the pharmacy to the proper PBM and then</p> <p>22 from the proper PBM to whoever the PBM's</p> <p>23 direct client is.</p> <p>24 Is that accurate?</p> <p>25 MR. STANOCH: Objection to</p>
<p style="text-align: right;">Page 135</p> <p>1 L. Craft</p> <p>2 by whoever its client is, right?</p> <p>3 MR. STANOCH: Objection to</p> <p>4 form.</p> <p>5 A. They care about lots of things.</p> <p>6 When you say they just want to get paid by</p> <p>7 whoever their client is, there's a lot more</p> <p>8 to this than that. They need to know</p> <p>9 whether they've got a plan that's regulated</p> <p>10 under Medicare, under Medicaid. They need</p> <p>11 to be able to generate reports of drug</p> <p>12 usage, of compliance with formulary rules.</p> <p>13 I don't know what you mean by</p> <p>14 they just want to get paid. Yeah, they want</p> <p>15 to get paid, but they've got a lot of</p> <p>16 business purposes that are being supported</p> <p>17 by this data.</p> <p>18 Q. So let me ask that question in</p> <p>19 a little bit different way.</p> <p>20 The NCPDP fields that you've</p> <p>21 referenced in paragraph 27 and the linking</p> <p>22 to additional fields that you refer to in</p> <p>23 27, the purpose of that is to direct the</p> <p>24 claim to the entity that will be paying the</p> <p>25 PBM directly; is that right?</p>	<p style="text-align: right;">Page 137</p> <p>1 L. Craft</p> <p>2 form.</p> <p>3 Compound.</p> <p>4 Unintelligible.</p> <p>5 Go ahead.</p> <p>6 A. I'm sorry. I can't -- I can't</p> <p>7 agree with your characterization that</p> <p>8 suggests that's all these data elements are</p> <p>9 used for because it's not. These data</p> <p>10 elements are used for all kinds of services</p> <p>11 performed by the PBM for underlying payors,</p> <p>12 so I can't -- I mean, certainly that is part</p> <p>13 of this.</p> <p>14 These numbers that you see</p> <p>15 here, these fields make it possible for the</p> <p>16 PBM to uniquely identify not only who is</p> <p>17 going to be writing a check, but to be able</p> <p>18 to structure the data that it sends to that</p> <p>19 client in a way that the client can then use</p> <p>20 it to bill any underlying TPP who is</p> <p>21 being -- who is being administered by an</p> <p>22 ASO.</p> <p>23 So there are lots of purposes</p> <p>24 for this and the point of the paragraph you</p> <p>25 were looking at a moment ago was merely to</p>

<p style="text-align: right;">Page 138</p> <p>1 L. Craft</p> <p>2 make the point that the data transmitted in</p> <p>3 this messaging system between the PBM and</p> <p>4 the pharmacy is not the entirety of the</p> <p>5 data. The PBM has incredibly rich data on</p> <p>6 its clients that are accessed and organized</p> <p>7 by the same fields and that can be</p> <p>8 identified.</p> <p>9 This is why when Mr. Kosty says</p> <p>10 well, you don't always at the pharmacy level</p> <p>11 write in the plan name, you don't need to</p> <p>12 because it automatically pops up. It locks</p> <p>13 into the data that the message -- that is</p> <p>14 included in the message sent by the pharmacy</p> <p>15 because these are relational databases</p> <p>16 maintained by the PBM that are linked and</p> <p>17 they're linked by using some of these</p> <p>18 numbers.</p> <p>19 So I hope that --</p> <p>20 Q. How are they -- sorry. I</p> <p>21 didn't mean to cut you off.</p> <p>22 What is the process to link --</p> <p>23 you used the term "link." Tell me more</p> <p>24 about that. What does that mean?</p> <p>25 A. Sure. So when we have the</p>	<p style="text-align: right;">Page 140</p> <p>1 L. Craft</p> <p>2 These are linked data tables that</p> <p>3 automatically generate claims data with the</p> <p>4 specifics I've just described using</p> <p>5 information that is supplied through the</p> <p>6 NCPDP messaging system.</p> <p>7 Q. Have you developed a system --</p> <p>8 have you ever developed a system to, as you</p> <p>9 say, automatically links these NCPDP fields</p> <p>10 with the other information that you're</p> <p>11 saying the PBM maintains?</p> <p>12 MR. STANOCH: Objection to</p> <p>13 form.</p> <p>14 A. There's no need for me to do</p> <p>15 so. It happens automatically. That's why</p> <p>16 the claims data that PBMs produce</p> <p>17 automatically includes this information.</p> <p>18 It's there by default.</p> <p>19 Q. Okay.</p> <p>20 Have you seen this process</p> <p>21 occur, like, within a PBM? I want to know</p> <p>22 have you ever actually seen this happen?</p> <p>23 MR. STANOCH: Objection.</p> <p>24 Seen it -- what?</p> <p>25 Vague.</p>
<p style="text-align: right;">Page 139</p> <p>1 L. Craft</p> <p>2 group member ID or cardholder ID, as its</p> <p>3 described in this diagram, and the BIN and</p> <p>4 PCN number, that is sufficient so that when</p> <p>5 the PBM gets the message, they -- the</p> <p>6 information there allows them to -- using</p> <p>7 those fields, that's going to take you to</p> <p>8 the -- to the client name, the client ID,</p> <p>9 the account number set up with the PBM, the</p> <p>10 account ID, the description of the group.</p> <p>11 So that data effectively --</p> <p>12 when we see claims data, all of that is</p> <p>13 populated, we see all of these fields. We</p> <p>14 see or we should. We should see client</p> <p>15 name, client ID, account number, account</p> <p>16 description, group number, group description</p> <p>17 or employer description. We should see all</p> <p>18 of those fields.</p> <p>19 What I'm saying to you is that</p> <p>20 the fact that not every one of those is</p> <p>21 written out in the pharmacy messaging system</p> <p>22 is irrelevant. They are automatically</p> <p>23 populated. It's not like there's someone</p> <p>24 sitting in a back room at a PBM matching up</p> <p>25 the incoming records with this other data.</p>	<p style="text-align: right;">Page 141</p> <p>1 L. Craft</p> <p>2 Ambiguous.</p> <p>3 Not to mention borderline</p> <p>4 argumentative, but go ahead.</p> <p>5 A. Well, I'm not sure what you</p> <p>6 mean by "seen it happen." It is an</p> <p>7 automated software process which is</p> <p>8 essential to the industry that it happened</p> <p>9 instantaneously. It is the backbone of</p> <p>10 clearing transactions. It's the backbone of</p> <p>11 claims adjudication. If it doesn't occur,</p> <p>12 then claims adjudication could not occur</p> <p>13 instantaneously because one needs to be able</p> <p>14 to determine the eligibility of the</p> <p>15 individual, the benefit structure, the</p> <p>16 formulary tier placement of the drug, the</p> <p>17 individual's recorded purchases previously</p> <p>18 in the year to determine whether there's an</p> <p>19 unpaid deductible or whether the individual</p> <p>20 has reached an out-of-pocket cap.</p> <p>21 All of this has to happen in</p> <p>22 seconds and the only way for that to occur</p> <p>23 is for what's coming from the pharmacy to</p> <p>24 automatically connect with, link with that</p> <p>25 data at the PBM in order to perform claims</p>

<p style="text-align: right;">Page 142</p> <p>1 L. Craft</p> <p>2 adjudication and instantly return a</p> <p>3 confirmation, including specific price and</p> <p>4 its decomposition between the TPP and the</p> <p>5 PBM.</p> <p>6 So I don't know what there</p> <p>7 is -- I've seen the byproduct of that</p> <p>8 because I've seen claims data over and over</p> <p>9 and over again and I know what it looks like</p> <p>10 and I've also seen messages from pharmacies</p> <p>11 back and forth using the NCPDP system. So</p> <p>12 I'm not sure what I would see. It's not</p> <p>13 like there's someone sitting there pressing</p> <p>14 buttons. It's not a business process that</p> <p>15 you watch take place.</p> <p>16 Q. Okay.</p> <p>17 So you mentioned it's an</p> <p>18 automated software process.</p> <p>19 Is there a name of the software</p> <p>20 that performs this?</p> <p>21 A. Everybody's got their own</p> <p>22 little proprietary name, but it's the claims</p> <p>23 adjudication software.</p> <p>24 Q. Okay.</p> <p>25 Do you know any of the names of</p>	<p style="text-align: right;">Page 144</p> <p>1 L. Craft</p> <p>2 industry standard?</p> <p>3 MR. STANOCH: Objection.</p> <p>4 Misstates testimony.</p> <p>5 Vague.</p> <p>6 Asked and answered.</p> <p>7 A. So the industry standard I'm</p> <p>8 talking about is -- let's not forget that</p> <p>9 the NCPDP portion of this called an industry</p> <p>10 standard. The NCPDP itself is a standard</p> <p>11 setting organization for the industry. Its</p> <p>12 procedures, including the switching systems</p> <p>13 that are used to carry these messages, are</p> <p>14 legally mandated to be observed under HIPAA.</p> <p>15 So I think all of those facts speak to</p> <p>16 standards.</p> <p>17 Now, what the PBMs do with that</p> <p>18 data in order to perform the claims</p> <p>19 adjudication function? The requirements of</p> <p>20 their TPP clients are absolutely the same</p> <p>21 regardless of which PBM you're going to.</p> <p>22 PBMs bid against each other to take clients</p> <p>23 from each other. The data must be</p> <p>24 consistent, it must be portable, it must be</p> <p>25 programmatic, it must be readily</p>
<p style="text-align: right;">Page 143</p> <p>1 L. Craft</p> <p>2 the proprietary ones?</p> <p>3 MR. STANOCH: Objection to</p> <p>4 form.</p> <p>5 A. It's just branding. The</p> <p>6 functions are the same because the business</p> <p>7 requirements are the same. Now, none occur</p> <p>8 to me off the top of my head, terms used by</p> <p>9 individual PBMs.</p> <p>10 But let's just revert to the</p> <p>11 fact that the essential business functions</p> <p>12 that have to be performed by those systems</p> <p>13 do not differ from one PBM to another. The</p> <p>14 incoming data and the outgoing data has to</p> <p>15 be consistent with the NCPDP format and the</p> <p>16 business function of adjudication has to be</p> <p>17 performed in the same way, taking into</p> <p>18 account the same elements and being able to</p> <p>19 generate the same kinds of outcomes,</p> <p>20 regardless of which PBM you're talking to.</p> <p>21 This is industry standard. This is not sui</p> <p>22 generis from one PBM to another.</p> <p>23 Q. Okay.</p> <p>24 So from where -- on what are</p> <p>25 you basing your claim that this is an</p>	<p style="text-align: right;">Page 145</p> <p>1 L. Craft</p> <p>2 interpretable and that's how, for example, a</p> <p>3 large TPP may say "You know what? If you</p> <p>4 don't improve my financial terms, PBM, I'm</p> <p>5 going to take my business to another PBM"</p> <p>6 and we're just going to literally on one day</p> <p>7 of a year, we're going to cut over to a new</p> <p>8 system.</p> <p>9 That could not be true if they</p> <p>10 weren't performing the same operations in a</p> <p>11 way that generated the same or similar</p> <p>12 outputs and of course their outputs do look</p> <p>13 the same or similar.</p> <p>14 Q. Have you ever actually</p> <p>15 discussed this automatic linking process</p> <p>16 with anybody at a PBM?</p> <p>17 MR. STANOCH: Objection to</p> <p>18 form.</p> <p>19 Vague.</p> <p>20 At a PBM?</p> <p>21 A. Well, I mean I certainly have</p> <p>22 sat in on a deposition from a representative</p> <p>23 of a PBM that addressed this and other</p> <p>24 topics about claims adjudication platforms.</p> <p>25 I have not sat down and personally had a</p>

<p style="text-align: right;">Page 146</p> <p>1 L. Craft</p> <p>2 discussion with someone. There is obviously</p> <p>3 a wealth of declarations filed in</p> <p>4 pharmaceutical cases over the last ten years</p> <p>5 where PBMs have stated under penalty of</p> <p>6 perjury that their process involved</p> <p>7 determination of the following fields. All</p> <p>8 consistent, across all of these PBMs, you</p> <p>9 will see little differences between them in</p> <p>10 how they even describe the process.</p> <p>11 I don't believe anyone says</p> <p>12 here's our specific software methodology for</p> <p>13 linking to the client file, nor does it</p> <p>14 matter. The bottom line is it doesn't. You</p> <p>15 get that data from all PBMs about client</p> <p>16 account group as part of the claims data.</p> <p>17 Q. I want to focus on the first</p> <p>18 half of the message, not client account</p> <p>19 group, but rather what we see here in figure</p> <p>20 three shown on your screen: Plan ID, group</p> <p>21 ID, BIN or now IIN number, processor,</p> <p>22 control number.</p> <p>23 Those data -- specifically,</p> <p>24 those data -- are not intended to identify</p> <p>25 TPA or ASO relationships, right?</p>	<p style="text-align: right;">Page 148</p> <p>1 L. Craft</p> <p>2 some cases that structure, when it is</p> <p>3 applied by the PBM is -- because this same</p> <p>4 structure is going to identify the</p> <p>5 particular client data product -- I</p> <p>6 shouldn't describe it as a data product</p> <p>7 because everybody is getting the same kind</p> <p>8 of information, but if you recall, I</p> <p>9 described earlier in my testimony today that</p> <p>10 the data a PBM sends to ASO clients must be</p> <p>11 structured in a way that is sufficient to</p> <p>12 delineate ASO business versus insured</p> <p>13 business. Data has to be sufficient to</p> <p>14 support that.</p> <p>15 Does it come with a label in</p> <p>16 every case that says this is an ASO, this is</p> <p>17 a TPA? No, it doesn't. But the data must</p> <p>18 be structured in a way that is sufficient</p> <p>19 not only to make that bifurcation between</p> <p>20 insured and TPA so that that can be</p> <p>21 implemented by the third party -- the</p> <p>22 administrator, that intermediary, but it</p> <p>23 must be sufficient to further decompose the</p> <p>24 data so that the data can be used by that</p> <p>25 ASO or TPA to bill its clients correctly, to</p>
<p style="text-align: right;">Page 147</p> <p>1 L. Craft</p> <p>2 (Reporter clarification)</p> <p>3 A. You've skipped highlighting</p> <p>4 cardholder ID on the left, which I would</p> <p>5 consider also one of the numeric fields</p> <p>6 that's relevant to this.</p> <p>7 MR. STANOCH: Ms. Craft, we</p> <p>8 lost you again --</p> <p>9 A. -- automatic literally the PBM</p> <p>10 to identify --</p> <p>11 MR. DORNER: Ms. Craft, I'm</p> <p>12 sorry. You cut out a second time. I</p> <p>13 apologize for interrupting you and</p> <p>14 cutting you off. Let's restart this</p> <p>15 whole procedure. Okay?</p> <p>16 We'll strike that question,</p> <p>17 we'll strike whatever answer we were</p> <p>18 able to hear and I'll ask it again.</p> <p>19 Q. The plan ID, group ID, BIN or</p> <p>20 now IIN number, processor control number and</p> <p>21 cardholder ID reflected in figure three of</p> <p>22 your report are not intended to identify ASO</p> <p>23 or TPA relationships.</p> <p>24 Is that right?</p> <p>25 A. Not true. Not true because in</p>	<p style="text-align: right;">Page 149</p> <p>1 L. Craft</p> <p>2 attribute the individual claims.</p> <p>3 What I'm telling you is that</p> <p>4 the data that the ASO or PBM gets -- I'm</p> <p>5 sorry -- the ASO or TPA gets from the PBM</p> <p>6 must be sufficient to perform that</p> <p>7 allocation.</p> <p>8 So the identification -- if</p> <p>9 what you mean is does the name -- the actual</p> <p>10 name of the underlying payor for an ASO</p> <p>11 always appear in that PBM data, the answer</p> <p>12 is no. Sometimes it does, sometimes it</p> <p>13 doesn't. But is it -- is this data</p> <p>14 sufficient that participants in the industry</p> <p>15 can automatically and programmatically sign</p> <p>16 these individual claims to clients of an ASO</p> <p>17 or TPA? Yes, it is. That's an essential</p> <p>18 business function.</p> <p>19 Q. So I appreciate the</p> <p>20 explanation, but I guess I want to go back</p> <p>21 to what -- I think my question was more</p> <p>22 directly getting at is, you know, these data</p> <p>23 shown here in figure three -- specifically,</p> <p>24 the card holder ID and all of the fields</p> <p>25 shown in the second column -- you're saying</p>

<p style="text-align: right;">Page 150</p> <p>1 L. Craft</p> <p>2 that those are designed to identify ASO and</p> <p>3 TPA relationships?</p> <p>4 MR. STANOCH: Objection to</p> <p>5 form.</p> <p>6 Misstates testimony.</p> <p>7 Asked and answered.</p> <p>8 A. I'm saying they must be capable</p> <p>9 of being used in that manner.</p> <p>10 Q. I'm sorry. I didn't hear that</p> <p>11 answer. It cut out.</p> <p>12 A. I said that they must be --</p> <p>13 these data fields must be capable of being</p> <p>14 used in that manner in combination so that</p> <p>15 the claims data, which is reported out to</p> <p>16 the client, can be used in the event of an</p> <p>17 ASO or TPA relationship to bill the</p> <p>18 underlying client.</p> <p>19 THE WITNESS: If you don't mind</p> <p>20 holding on for just 20 seconds here,</p> <p>21 I'm going to email my tech guy and ask</p> <p>22 why we're having internet instability</p> <p>23 because I do apologize for that.</p> <p>24 That's extraordinarily rare and --</p> <p>25 MR. DORNER: That's fine.</p>	<p style="text-align: right;">Page 152</p> <p>1 L. Craft</p> <p>2 THE WITNESS: I actually have</p> <p>3 sent the message. It's done. I'm</p> <p>4 ready.</p> <p>5 MR. DORNER: Well, didn't we</p> <p>6 agree you wouldn't communicate with</p> <p>7 anybody on the record, Ms. Craft?</p> <p>8 MR. STANOCH: Hold on. Mr.</p> <p>9 Dorner -- no, no. Ms. Craft, stop.</p> <p>10 Mr. Dorner, first, I don't</p> <p>11 appreciate the smirk. Second, I don't</p> <p>12 appreciate you're saying when Ms. Craft</p> <p>13 is asking her IT person, as she said,</p> <p>14 to help with an internet issue for the</p> <p>15 Zoom deposition -- I do not</p> <p>16 believe that's appropriate --</p> <p>17 MR. DORNER: Can we go off the</p> <p>18 record?</p> <p>19 MR. STANOCH: No. I'm not off</p> <p>20 the record.</p> <p>21 MR. DORNER: We're off the</p> <p>22 record.</p> <p>23 MR. STANOCH: We're going to</p> <p>24 keep going. We're not going off the</p> <p>25 record. We don't agree.</p>
<p style="text-align: right;">Page 151</p> <p>1 L. Craft</p> <p>2 Let's go off the record then</p> <p>3 and you could do that.</p> <p>4 THE WITNESS: Literally 20</p> <p>5 seconds.</p> <p>6 MR. DORNER: It's okay. Let's</p> <p>7 take a quick five. Let's go off.</p> <p>8 MR. STANOCH: No, Drew. The</p> <p>9 witness doesn't want to go off the</p> <p>10 record. We are going to keep going.</p> <p>11 MR. DORNER: Well, I do, Dave,</p> <p>12 so we're going off the record.</p> <p>13 Five minutes.</p> <p>14 THE WITNESS: Well, can I</p> <p>15 just --</p> <p>16 MR. STANOCH: Wait. Hold on.</p> <p>17 I'm not agreeing to go off the record,</p> <p>18 Mr. Dorner.</p> <p>19 The witness is trying to</p> <p>20 accommodate you with internet and said</p> <p>21 she needs to do something, much like</p> <p>22 you refer to things and look at things</p> <p>23 while you're doing it. She does not</p> <p>24 need a break now. She's ready to</p> <p>25 proceed. We can proceed.</p>	<p style="text-align: right;">Page 153</p> <p>1 L. Craft</p> <p>2 MR. DORNER: Please take us off</p> <p>3 the record.</p> <p>4 MR. STANOCH: We're not</p> <p>5 agreeing to go off the record.</p> <p>6 THE VIDEOGRAPHER: Counsel, I</p> <p>7 need you to agree.</p> <p>8 MR. STANOCH: We need to agree.</p> <p>9 I don't agree, Mr. Dorner.</p> <p>10 The witness is ready to</p> <p>11 proceed.</p> <p>12 MR. DORNER: Why not? What if</p> <p>13 I want a break?</p> <p>14 MR. STANOCH: We're on the</p> <p>15 record, Mr. Dorner.</p> <p>16 MR. DORNER: Well, I'd like to</p> <p>17 go refill my water because it's empty.</p> <p>18 So may I please go off the record, Mr.</p> <p>19 Stanoch?</p> <p>20 MR. STANOCH: Mr. Dorner, we're</p> <p>21 ready to proceed.</p> <p>22 MR. DORNER: May I please go</p> <p>23 off the record, Mr. Stanoch, so I can</p> <p>24 refill my water so my throat doesn't</p> <p>25 dry out?</p>

<p style="text-align: right;">Page 154</p> <p>1 L. Craft</p> <p>2 MR. STANOCH: Mr. Dorner, why</p> <p>3 don't you go a few more minutes or have</p> <p>4 one of the five people in your room</p> <p>5 help you out?</p> <p>6 MR. DORNER: Well, there's</p> <p>7 not five people and I'd like to go off</p> <p>8 the record. But if -- are you forcing</p> <p>9 me to stay on?</p> <p>10 MR. STANOCH: I'm saying the</p> <p>11 witness has said she prefers to</p> <p>12 continue with the questioning and to</p> <p>13 proceed.</p> <p>14 MR. DORNER: And I prefer to</p> <p>15 take a quick break. Okay?</p> <p>16 MR. STANOCH: I'm not -- we're</p> <p>17 on the record, Mr. Dorner. Why don't</p> <p>18 we go a few more minutes at the</p> <p>19 witness's request?</p> <p>20 MR. DORNER: All right.</p> <p>21 We're going to go about three</p> <p>22 more hours on the record and we're not</p> <p>23 stopping.</p> <p>24 Q. All right, Ms. Craft.</p> <p>25 Pharmaceutical wholesalers are</p>	<p style="text-align: right;">Page 156</p> <p>1 L. Craft</p> <p>2 Q. Wholesalers don't have direct</p> <p>3 relationship with TPPS at all, right?</p> <p>4 MR. STANOCH: Objection to</p> <p>5 form.</p> <p>6 A. That's not necessarily true.</p> <p>7 Q. Why not?</p> <p>8 A. A TPP might have a relationship</p> <p>9 with a wholesaler. That's not impossible.</p> <p>10 But I don't think it's germane to this issue</p> <p>11 when your basic premise is correct, that</p> <p>12 wholesalers have separate relationships with</p> <p>13 manufacturers from whom they purchase</p> <p>14 product and pharmacies to whom they sell</p> <p>15 product and they are not directly</p> <p>16 contracting to sell product to third-party</p> <p>17 payers.</p> <p>18 I just -- I want to make clear</p> <p>19 that there are instances -- so, for example,</p> <p>20 you can have a clinic that direct -- that</p> <p>21 purchases product to be then dispensed to</p> <p>22 its patients that contracts to get that</p> <p>23 product from a wholesaler.</p> <p>24 MR. DORNER: Take down figure</p> <p>25 three and move on to page 17 to 18 of</p>
<p style="text-align: right;">Page 155</p> <p>1 L. Craft</p> <p>2 not involved in the contracting process</p> <p>3 between potential class member TPPs, and</p> <p>4 their PBMs, ASOs or third-party</p> <p>5 administrators.</p> <p>6 Isn't that right?</p> <p>7 MR. STANOCH: Objection to</p> <p>8 form.</p> <p>9 A. Would you mind reading that</p> <p>10 back? It sounds like you got it very</p> <p>11 precisely written. I just -- you spoke</p> <p>12 quite quickly and I want to make sure I've</p> <p>13 got your question correctly.</p> <p>14 Q. Sure.</p> <p>15 What I'm asking is you</p> <p>16 wholesalers for pharmaceuticals are not</p> <p>17 involved in the contracting process between</p> <p>18 TPPs and either PBMs or other</p> <p>19 intermediaries.</p> <p>20 MR. STANOCH: Objection to</p> <p>21 form.</p> <p>22 A. Yes. I think your basic</p> <p>23 premise is correct, which is that the TPP's</p> <p>24 contract with PBMs and that is separate from</p> <p>25 the relationship with wholesalers.</p>	<p style="text-align: right;">Page 157</p> <p>1 L. Craft</p> <p>2 your report. We can put those side by</p> <p>3 side.</p> <p>4 Q. All right.</p> <p>5 Ms. Craft, paragraph 29</p> <p>6 introduces a table that you say shows the</p> <p>7 share of total US prescriptions processed I</p> <p>8 believe by six of the largest PBMs from 2015</p> <p>9 to 2018, including entities that they've</p> <p>10 subsequently acquired or merged with.</p> <p>11 Let me ask a question first.</p> <p>12 This table is not specific to</p> <p>13 valsartan, correct?</p> <p>14 A. That's correct.</p> <p>15 Q. Have you done any analysis or</p> <p>16 study with respect to whether the percentage</p> <p>17 of VCD prescriptions of the top six PBMs</p> <p>18 processed is equivalent or commensurate with</p> <p>19 the amount of prescriptions that the top six</p> <p>20 PBMs overall handle?</p> <p>21 MR. STANOCH: Objection to</p> <p>22 form.</p> <p>23 Vague.</p> <p>24 Ambiguous.</p> <p>25 Compound.</p>

<p style="text-align: right;">Page 158</p> <p>1 L. Craft</p> <p>2 A. I would expect it to be at</p> <p>3 least as high as reported here and that's</p> <p>4 based on the fact that the VCDs in question</p> <p>5 here were -- the frequency of cash purchases</p> <p>6 was quite small, which is to say that in the</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 You see the numbers for all</p> <p>11 other PBMs in cash in the bottom row here,</p> <p>12 right? So cash prescription purchases in</p> <p>13 general are higher than the rate that we see</p> <p>14 for these VCDs. So that's one fact.</p> <p>15 The other is if we want to look</p> <p>16 at discount plans as another form of cash</p> <p>17 purchase because consumers pay the entirety</p> <p>18 of the price, those are quite small too for</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 So the fact that there's</p> <p>22 comparatively little cash purchasing by</p> <p>23 comparison to the industry metrics here</p> <p>24 would suggest to me you're going to have</p> <p>25 more claims adjudication on behalf of</p>	<p style="text-align: right;">Page 160</p> <p>1 L. Craft</p> <p>2 are being dispensed and you can apply those</p> <p>3 PBM specific metrics to come up with</p> <p>4 something pretty close to what you see in</p> <p>5 this table, which is put together and</p> <p>6 published by Drug Channels Institute.</p> <p>7 Q. Why did you limit your table to</p> <p>8 2015 to 2018?</p> <p>9 A. Because the published data --</p> <p>10 first of all, I understood that the recalls</p> <p>11 were happening starting in 2018 and the data</p> <p>12 was readily available from a consistent</p> <p>13 source, although as you see in the footnote,</p> <p>14 we had to make an adjustment for 2015</p> <p>15 because of a difference in reporting</p> <p>16 methodology.</p> <p>17 But it was available from Drug</p> <p>18 Channels Institute for 2015, 2016, 2017,</p> <p>19 2018 and to assure consistency, we wanted to</p> <p>20 stay with a single source of data.</p> <p>21 Q. You're aware, though, that the</p> <p>22 claims period in this case goes back to 2012</p> <p>23 aren't you?</p> <p>24 A. Yes, but the reason that these</p> <p>25 numbers are the relevant ones and not the</p>
<p style="text-align: right;">Page 159</p> <p>1 L. Craft</p> <p>2 third-party payers and that generally goes</p> <p>3 through the big PBMs.</p> <p>4 Q. What are you basing that last</p> <p>5 part of your statement on, that it generally</p> <p>6 goes through the big PBMs?</p> <p>7 A. The data you see here in this</p> <p>8 table, which is sourced with a standard</p> <p>9 industry summary that is generated or was</p> <p>10 generated on an annual basis.</p> <p>11 And I would point out that the</p> <p>12 underlying source of this data -- and you</p> <p>13 can come pretty close to replicating these</p> <p>14 numbers -- is the publically filed</p> <p>15 financials of PBMs, what they report, claims</p> <p>16 lines processed and they convert those to</p> <p>17 equivalent prescriptions in most cases,</p> <p>18 which is to say a 30-day prescription as</p> <p>19 opposed to a 90-day -- so a 90 would count</p> <p>20 as three 30s -- so that they are</p> <p>21 standardized metrics and they report in</p> <p>22 general the number of claims that they have</p> <p>23 processed on that basis.</p> <p>24 So you can take data on the</p> <p>25 total number of prescriptions in the US that</p>	<p style="text-align: right;">Page 161</p> <p>1 L. Craft</p> <p>2 share that was processed by each of these</p> <p>3 PBMs in 2012, '13 or '14 is that the growing</p> <p>4 share, the concentration in these PBMs is</p> <p>5 the result of industry consolidation. So</p> <p>6 PBMs, the more diffuse list, the more</p> <p>7 numerous list of PBMs operating in 2012, '13</p> <p>8 and '14, for example, becomes shorter with</p> <p>9 each passing year as these smaller PBMs are</p> <p>10 gobbled up by bigger PBMs and what happens</p> <p>11 when those smaller PBMs are gobbled up is</p> <p>12 that their data is transferred to the</p> <p>13 acquirer, PBMs 1 through 6 on this list.</p> <p>14 So the data for those earlier</p> <p>15 periods doesn't get burned and thrown away.</p> <p>16 It is part of -- it is an essential asset in</p> <p>17 the acquisition of the PBM. It has enormous</p> <p>18 value and so that data -- what I was</p> <p>19 attempting to illustrate here is that the</p> <p>20 targeted data sources -- and I'm just here</p> <p>21 illustrating top six PBMs -- possess the</p> <p>22 data for a huge amount of the market and</p> <p>23 they have acquired data over time from the</p> <p>24 entities that they absorbed.</p> <p>25 So the value of this data is</p>

<p style="text-align: right;">Page 162</p> <p>1 L. Craft</p> <p>2 rather exuberantly and nicely demonstrated,</p> <p>3 the article "Merger Mania" from Mr. Kosty</p> <p>4 and his organization that talks about how</p> <p>5 these acquisitions are so valuable because</p> <p>6 of greater acts of data.</p> <p>7 Q. Now, when you refer to the data</p> <p>8 that PBMs are acquiring from, I guess,</p> <p>9 targets in those transactions, is it your</p> <p>10 testimony that the acquired data is merged</p> <p>11 in in every case into the acquiring PBM</p> <p>12 system?</p> <p>13 MR. STANOCH: Objection.</p> <p>14 Q. In other words, it's made</p> <p>15 completely uniform?</p> <p>16 MR. STANOCH: Objection to</p> <p>17 form.</p> <p>18 Vague and ambiguous.</p> <p>19 Go ahead.</p> <p>20 A. No, that's not my testimony.</p> <p>21 It is possible for there to -- for the data</p> <p>22 to continue to be independently on an</p> <p>23 independent platform. It's not essential</p> <p>24 that it all be merged.</p> <p>25 So, for example, a PBM has a</p>	<p style="text-align: right;">Page 164</p> <p>1 L. Craft</p> <p>2 revenue and their data has already largely</p> <p>3 been produced.</p> <p>4 My first question is so in</p> <p>5 contrast to your estimate of PBM market</p> <p>6 share, pharmacies you're not measuring on</p> <p>7 number of prescriptions, but rather by</p> <p>8 revenue.</p> <p>9 Is that accurate?</p> <p>10 A. Yes.</p> <p>11 Q. So aren't -- I mean, revenue</p> <p>12 and prescription volume are two very</p> <p>13 different metrics, are they not?</p> <p>14 MR. STANOCH: Objection to</p> <p>15 form.</p> <p>16 A. They are different metrics.</p> <p>17 Q. And I believe you say here that</p> <p>18 the revenues here also include specialty</p> <p>19 drugs and mail order and storefront sales.</p> <p>20 So what's your basis for saying</p> <p>21 that the revenue can be a proxy for the</p> <p>22 share of proposed class transaction?</p> <p>23 MR. STANOCH: Objection to</p> <p>24 form.</p> <p>25 Go ahead.</p>
<p style="text-align: right;">Page 163</p> <p>1 L. Craft</p> <p>2 much greater interest in merging that</p> <p>3 ongoing client relationships as opposed to</p> <p>4 closed client relationships.</p> <p>5 My testimony is that the data</p> <p>6 still exists and the mere fact that it got</p> <p>7 put on an archival hard storage device</p> <p>8 doesn't change the data. So it may mean</p> <p>9 delivering -- so, for example, with Optum, I</p> <p>10 sometimes get a Catamaran production and an</p> <p>11 Optum RX production that is without</p> <p>12 Catamaran, a large PBM that it acquired.</p> <p>13 I will tell you that their</p> <p>14 field names are exactly the same. The data</p> <p>15 is reported exactly the same way, but</p> <p>16 it's -- they're sometimes produced</p> <p>17 separately.</p> <p>18 Q. Let's go to paragraph 31 of</p> <p>19 your report -- there is it is, page 19.</p> <p>20 Thank you.</p> <p>21 Now here, paragraph 31 is</p> <p>22 talking about pharmacies and it's saying the</p> <p>23 top nine retail pharmacies collectively</p> <p>24 accounted for approximately 72% of the</p> <p>25 nation's prescription drug dispensing</p>	<p style="text-align: right;">Page 165</p> <p>1 L. Craft</p> <p>2 A. The fact that it is frequently</p> <p>3 used as a proxy and that there's not readily</p> <p>4 available data from the pharmacies in public</p> <p>5 sources telling us the number of</p> <p>6 prescriptions that they filled. However, in</p> <p>7 this case, you happen to have the retailer</p> <p>8 defendant/pharmacy defendant data that quite</p> <p>9 specifically enumerates each individual</p> <p>10 prescription of the contested products</p> <p>11 and the -- and tells us exactly how much</p> <p>12 they dispensed for over the -- over the</p> <p>13 class period.</p> <p>14 So we know the actual number</p> <p>15 and if you wanted to compare that number to</p> <p>16 the total prescriptions reported by those</p> <p>17 retailer defendants to the total volume sold</p> <p>18 for those same NDCs from the Xponent data,</p> <p>19 you could certainly do that and compute that</p> <p>20 percentage. I have not done that, but</p> <p>21 certainly one could.</p> <p>22 Q. And that was going to be my</p> <p>23 next question.</p> <p>24 You haven't actually taken the</p> <p>25 pharmacy data produced in this case to see</p>

<p style="text-align: right;">Page 166</p> <p>1 L. Craft</p> <p>2 if it actually accounts for 72% of the</p> <p>3 nation's valsartan drug dispensing drug</p> <p>4 dispenses, right?</p> <p>5 A. I have not, but that could be</p> <p>6 done quite straightforwardly using the</p> <p>7 Xponent data.</p> <p>8 Q. Now, if we go to paragraph 32,</p> <p>9 here you say if you -- basically, if you</p> <p>10 collected data from the top six PBMs and the</p> <p>11 top nine pharmacies, that could be expected</p> <p>12 to cover up to 98% of class purchases as</p> <p>13 illustrated in figure six.</p> <p>14 You say could be expected to</p> <p>15 cover up 98%. You haven't actually</p> <p>16 performed this calculation, right?</p> <p>17 A. No. I've performed the</p> <p>18 calculation that gives you that result, the</p> <p>19 98% result. If what you're saying is do I</p> <p>20 have the data from the largest PBMs, no,</p> <p>21 I've made clear I don't have that data.</p> <p>22 Q. In the past, for any other</p> <p>23 case, have you collected data from the top</p> <p>24 six PBMs and the top nine pharmacies to</p> <p>25 determine what percentage of claims they</p>	<p style="text-align: right;">Page 168</p> <p>1 L. Craft</p> <p>2 think this is a good approximation.</p> <p>3 Q. I asked you a moment ago about</p> <p>4 whether or not you've obtained data from all</p> <p>5 the entities in this table of your report.</p> <p>6 I want to think a little bit more broadly</p> <p>7 about a similar question.</p> <p>8 Has On Point or you ever</p> <p>9 actually obtained claims data of the type</p> <p>10 you're proposing to use in this case just</p> <p>11 from the top six PBMs shown in table five?</p> <p>12 MR. STANOCH: Objection to</p> <p>13 form.</p> <p>14 Again, caution the witness not</p> <p>15 to divulge any information subject to a</p> <p>16 confidentiality or consulting</p> <p>17 arrangement in any other case, but you</p> <p>18 may attempt to answer.</p> <p>19 A. I have received -- I have</p> <p>20 received -- I believe your question is in</p> <p>21 any single case do I have data from all six</p> <p>22 of the top PBMs.</p> <p>23 Am I correctly understanding</p> <p>24 your question?</p> <p>25 Q. Let's go with that one first,</p>
<p style="text-align: right;">Page 167</p> <p>1 L. Craft</p> <p>2 handled for any given pharmaceutical</p> <p>3 product?</p> <p>4 MR. STANOCH: Objection.</p> <p>5 Just caution the witness not to</p> <p>6 divulge anything that may be subject to</p> <p>7 a confidentiality order in a different</p> <p>8 case, but you may try to answer.</p> <p>9 A. I have not yet in any case I've</p> <p>10 worked on received that complete production.</p> <p>11 Q. Why do you use the phrase "up</p> <p>12 to 98%"?</p> <p>13 A. Because these are averages that</p> <p>14 are giving rise to this number, so I want to</p> <p>15 be conservative. I don't want to give you</p> <p>16 the impression that I'm saying it's going to</p> <p>17 be exactly 98%. There's going to be some</p> <p>18 variation around the particular products,</p> <p>19 but based on these industry shares, I would</p> <p>20 expect it to be up to 98%.</p> <p>21 And the other reason is that</p> <p>22 I'm using here the 2018 data and so if there</p> <p>23 was a less concentrated coverage of these</p> <p>24 drugs in earlier years, I would like to</p> <p>25 account for that as a possibility, but I</p>	<p style="text-align: right;">Page 169</p> <p>1 L. Craft</p> <p>2 sure.</p> <p>3 A. Yeah. Okay.</p> <p>4 So the answer is yes on a</p> <p>5 rolling production basis, which is currently</p> <p>6 based on subsets or samples of the data and</p> <p>7 which is being augmented and I'm not at</p> <p>8 liberty to discuss that case or to divulge</p> <p>9 any further details about it.</p> <p>10 Q. I won't ask you about the</p> <p>11 specifics of the case.</p> <p>12 I'll ask you this: Have you</p> <p>13 actually merged the data from all the PBMs</p> <p>14 that you received? Have you merged it into</p> <p>15 one data set?</p> <p>16 MR. STANOCH: Objection to</p> <p>17 form.</p> <p>18 Vague and ambiguous.</p> <p>19 Same caution.</p> <p>20 Please proceed.</p> <p>21 A. So that procedure went away.</p> <p>22 The final production, I have identified the</p> <p>23 procedures that would be used to account</p> <p>24 for, which principally -- these are very</p> <p>25 straightforward. These are data processing</p>

<p style="text-align: right;">Page 170</p> <p>1 L. Craft</p> <p>2 exercises that exist in almost any large</p> <p>3 commercial litigation, certainly antitrust</p> <p>4 cases and anything in pharma. This is</p> <p>5 nothing new to pharma, nothing specific to</p> <p>6 pharma.</p> <p>7 But when you get multisource</p> <p>8 data, one of the things that you do is in</p> <p>9 processing that data, you rename fields</p> <p>10 where they represent the same thing, you</p> <p>11 give them all a constant name. So six PBMs,</p> <p>12 if one abbreviates the ingredient cost and</p> <p>13 another calls it drug cost and another</p> <p>14 spells it out, you reconcile all of those</p> <p>15 and harmonize them. So it's a softer</p> <p>16 process that involves just changing the name</p> <p>17 so they're all the same.</p> <p>18 I have specified the procedures</p> <p>19 for that and reviewed all six and more PBM</p> <p>20 data sets to assure that all of the</p> <p>21 essential fields were present and to go back</p> <p>22 and ask for missing fields if they were</p> <p>23 needed. So I haven't actually programmed</p> <p>24 it. I basically vetted the procedures for</p> <p>25 doing so and identified any complications</p>	<p style="text-align: right;">Page 172</p> <p>1 L. Craft</p> <p>2 Then the data you've received</p> <p>3 does not include, I believe, what we termed</p> <p>4 as the set up documents. Do you remember</p> <p>5 what I'm talking about?</p> <p>6 A. Yeah. Yes, I do. It does not</p> <p>7 include plan set up worksheets.</p> <p>8 Q. Okay.</p> <p>9 Do you have an estimate for how</p> <p>10 long it would take in this case to merge</p> <p>11 data from the six PBMs and nine pharmacies</p> <p>12 in table four to make it uniform for the</p> <p>13 entire seven-year period?</p> <p>14 MR. STANOCH: Objection.</p> <p>15 Form.</p> <p>16 Vague and ambiguous.</p> <p>17 A. So first of all, it is not</p> <p>18 clear to me what the purpose of merging the</p> <p>19 data would be for ascertainability. So, for</p> <p>20 example, when I think of the objectives</p> <p>21 associated with ascertainability, one might</p> <p>22 say I want to identify an individual class</p> <p>23 member, but that's different from saying I</p> <p>24 want to know exactly how many prescriptions</p> <p>25 a particular TPP wrote.</p>
<p style="text-align: right;">Page 171</p> <p>1 L. Craft</p> <p>2 that needed to be resolved through data</p> <p>3 production.</p> <p>4 Q. The PBM -- and again, I'm not</p> <p>5 asking for the specifics of the case. I</p> <p>6 understand there are confidentiality</p> <p>7 concerns.</p> <p>8 Speaking generally about the</p> <p>9 PBM data that you say you -- or the samples</p> <p>10 of PBM data that you have received, are</p> <p>11 fully insured plans -- ASOs, TPAs -- are</p> <p>12 those either shown in those data -- well,</p> <p>13 let me break it down.</p> <p>14 Are TPA or ASOs shown in those</p> <p>15 data from every single PBM that you have</p> <p>16 collected from?</p> <p>17 MR. STANOCH: Objection to</p> <p>18 form.</p> <p>19 Same caution.</p> <p>20 A. Sometimes that information is</p> <p>21 present and sometimes it is not. As an</p> <p>22 explicit identifier that you can read and as</p> <p>23 a lawyer looking at it say yeah, it says</p> <p>24 here fully insured or it says here TPA.</p> <p>25 Q. I think I understand.</p>	<p style="text-align: right;">Page 173</p> <p>1 L. Craft</p> <p>2 Participation in class is gated</p> <p>3 for TPPs is gated based on the payor having</p> <p>4 paid for at least one prescription. So the</p> <p>5 objective of merging data from the</p> <p>6 perspective of the TPP clients is not clear</p> <p>7 to me why we would need to do that.</p> <p>8 I mean, of course it's</p> <p>9 interesting and nice to have a clean and</p> <p>10 consistent data set that rolls everything up</p> <p>11 into one big package, but it's not really</p> <p>12 necessary. So when you say how long would</p> <p>13 it take you to do it, I would ask the</p> <p>14 question first do we need to do it, do we</p> <p>15 need to merge all of the PBM data sets.</p> <p>16 The only place that this</p> <p>17 becomes relevant, in my opinion, for this</p> <p>18 specific factual configuration is where</p> <p>19 we're looking at the medical monitoring</p> <p>20 class because the same can be said of the</p> <p>21 economic damage class for consumers, right?</p> <p>22 If I paid for a prescription of a contested</p> <p>23 product, I'm in the class for economic</p> <p>24 damages.</p> <p>25 The medical monitoring is the</p>

Page 174

1 L. Craft
 2 only place, I believe, where there's a need
 3 to combine multiple transactions for a given
 4 consumer -- and that's not TPP, that's just
 5 consumer -- and to link those transactions
 6 so that we know how much product was
 7 actually purchased by those consumers,
 8 dispensed to them of particular dosage
 9 strengths over the class period.
 10 So I hope that answered your
 11 question. I don't know how long it would
 12 take to merge all six PBMs' data, but I'm
 13 not sure we would have the need. If we
 14 wanted to doubt for the purpose of linking
 15 records for individual consumers, we'd
 16 probably just extract the consumer
 17 identifying information from the PBM data
 18 and then merge that, which would be a
 19 smaller set of the data -- right? -- because
 20 we're just looking at the consumer
 21 participation and trying to figure out how
 22 much product they bought and of what
 23 particular dosage forms and strengths.
 24 Q. So you focused on medical
 25 monitoring class, but I didn't actually hear

Page 175

1 L. Craft
 2 an amount of time in that whole answer, so
 3 I'll ask it again.
 4 How long would it take to merge
 5 for the medical monitoring class, like you
 6 said? How long would it take to compile all
 7 that data and match up everybody's
 8 prescription records within the PBM data set
 9 so as to follow your methodology for the
 10 medical monitoring class?
 11 MR. STANOCH: Objection to
 12 form.
 13 Mischaracterizes testimony.
 14 Asked and answered.
 15 Hopelessly compound.
 16 Vague and ambiguous.
 17 You may try to answer.
 18 A. Okay. Well, I didn't
 19 understand your question to go to medical
 20 monitoring. I merely answered it in that
 21 fashion because I don't see the utility of
 22 merging the data, so to tell you how long it
 23 would take, other than for this single
 24 purpose, is a meaningless answer. I haven't
 25 thought about it because I don't know that

Page 176

1 L. Craft
 2 we would need to do it.
 3 For the medical monitoring
 4 class, if you're saying how long would it
 5 take to extract all the consumer purchases
 6 once their personal identifying information
 7 is supplied and then attempt to match
 8 identities across the PBMs -- the six PBMs'
 9 productions -- maybe a month. It depends
 10 upon how many levels of how perfect we want
 11 to be with our identity matching.
 12 I think we would start with a
 13 rules-based algorithm that would give us
 14 perfect matches and we would see what
 15 percentage we achieved with perfect matches.
 16 We would then probably go to what's called a
 17 fuzzy match that would allow, for example,
 18 changes in last name and see how much more
 19 we got.
 20 So there would be a couple of
 21 iterations of name matching processes. We
 22 would be obviously keying off of date of
 23 birth, location and whatever other
 24 personally identifying information is
 25 present.

Page 177

1 L. Craft
 2 Q. Let's shift gears here and go
 3 to paragraph 20 -- let's go back and go to
 4 paragraph 29 of your report. Actually,
 5 let's blow up note 30 rather than paragraph
 6 29. Footnote 30. There we go.
 7 All right, in this footnote
 8 here, you talk about the use of IRS Form
 9 5500 as a way of identifying third-party
 10 payors.
 11 Now, I want to make clear you
 12 didn't actually review any IRS Form 5500
 13 data in this matter in forming your opinion;
 14 is that right?
 15 A. That's correct.
 16 Q. Not all plan sponsors are
 17 required to file a Form 5500, are they?
 18 A. No. There are exceptions for
 19 small population -- small employers who meet
 20 certain requirements.
 21 Q. And you'd agree that Form 5500
 22 just on their own aren't sufficient to
 23 identify a proposed TPP class member; is
 24 that right?
 25 MR. STANOCH: Objection to

Page 178

1 L. Craft
2 form.
3 A. It certainly wouldn't identify
4 them as the best source of that information,
5 but what you see in this footnote is the
6 discussion of how claims administrators have
7 built databases of TPPs that originally at
8 their core were developed off of Form 5500
9 data but are supplemented, clarified,
10 augmented with new data every year and with
11 every case that the claims administrators
12 handle.
13 So we -- this is not the first
14 rodeo in pharmaceutical litigation. There
15 have been enumerable litigations that have
16 resulted in favorable judgments or
17 settlements that require distribution to
18 class members and there are established
19 processes for providing notice to those
20 class members and for managing their claims.
21 A lot of that does get updated based on Form
22 5500 data. It is not data that I would
23 anticipate using to identify TPPs in this
24 case.
25 Q. Okay.

Page 179

1 L. Craft
2 Given that, then you also
3 referred to claims administrators and pharma
4 end payor cases who have over time compiled
5 their own list of TPPs in operation each
6 year.
7 Do you see what I'm referring
8 to there in note 30?
9 A. Yes. That's actually what I
10 was referring to as well.
11 Q. Okay. Okay.
12 You haven't attached any of
13 those lists to your report or even -- right?
14 A. No. They don't belong to me.
15 They are the property and the work product
16 and the accumulated knowledge of the
17 established claims administrators who work
18 in this pharmaceutical field.
19 Q. So I guess I'm confused about
20 their purpose. Would you try to -- as part
21 of your methodology for identifying class
22 members, would you reach out, try to obtain
23 this list and then take names from it?
24 A. I don't foresee any need to do
25 that. I am saying there are these secondary

Page 180

1 L. Craft
2 sources that claims administrators structure
3 their notices using these lists and they
4 structure their claims administration
5 processes in part using these lists.
6 What I've outlined in this
7 report and what I've been outlining in the
8 course of my deposition today is what I
9 think is the most efficient and reliable
10 method to come up with a list of class
11 members and I'm merely saying this isn't the
12 only place where you get that information.
13 I'm just being asked to recommend a
14 methodology that works.
15 Q. So do you know whether you
16 would need to use these lists from other
17 cases in identifying the class in this case?
18 MR. STANOCH: Objection to
19 form.
20 Asked and answered.
21 Misstates testimony.
22 Go ahead.
23 A. Well, I struggle a bit with
24 your word "need" because it may be useful --
25 the counsel and the court may decide to use

Page 181

1 L. Craft
2 such lists in generating notices or other
3 purposes. The process I've outlined here
4 does not contemplate my having to access or
5 use those list.
6 Q. But if you need to, then you'll
7 obtain and use them if the need arises?
8 MR. STANOCH: Objection.
9 A. Or the claims administrator.
10 So, for example, the claims
11 administrator might access its own list to
12 make sure we don't miss any TPPs who should
13 be allowed to participate in the class.
14 That doesn't necessarily mean they turn it
15 over to me. They may do that themselves.
16 This is work product developed over, you
17 know, decades of time.
18 Q. Have you ever used lists from
19 other cases in identifying class payors in
20 the past?
21 MR. STANOCH: Objection.
22 Q. Excuse me. Identifying class
23 members in the past.
24 A. Lists from other -- no.
25 MR. DORNER: Mr. Stanoch, do I

<p style="text-align: right;">Page 182</p> <p>1 L. Craft</p> <p>2 have your permission to go off the</p> <p>3 record now?</p> <p>4 MR. STANOCH: Mr. Dorner, I</p> <p>5 don't appreciate the cheekiness.</p> <p>6 Ms. Craft, would you be</p> <p>7 comfortable with a break at this</p> <p>8 juncture?</p> <p>9 THE WITNESS: That would be</p> <p>10 fine. Could we make this our 20-minute</p> <p>11 lunch break? Is that acceptable to</p> <p>12 all? We get here back promptly in 20.</p> <p>13 Is that workable?</p> <p>14 MR. DORNER: I'm probably going</p> <p>15 to go longer than 20.</p> <p>16 THE WITNESS: Can you please</p> <p>17 tell me what you need in terms of a</p> <p>18 break, since this is clearly being</p> <p>19 driven by your schedule, not mine.</p> <p>20 MR. DORNER: We'll take a half</p> <p>21 hour.</p> <p>22 THE VIDEOGRAPHER: The time is</p> <p>23 11:55.</p> <p>24 This ends media unit three.</p> <p>25 We're going off the record.</p>	<p style="text-align: right;">Page 184</p> <p>1 L. Craft</p> <p>2 This is going to be on page 22,</p> <p>3 Ms. Craft.</p> <p>4 A. Okay.</p> <p>5 Q. In this paragraph, you say that</p> <p>6 the DSCSA was inactive in 2013 and is still</p> <p>7 not fully operative.</p> <p>8 What do you mean by not</p> <p>9 operative?</p> <p>10 A. Well, what I mean by not fully</p> <p>11 operative is that pharmacies obtained a</p> <p>12 number of extensions in terms of the</p> <p>13 effective date of the law and I believe the</p> <p>14 implementing regulations and the -- so there</p> <p>15 are some provisions of the law that are not</p> <p>16 yet enforced.</p> <p>17 Q. So, for example, one of the</p> <p>18 exemptions is that -- really from 2012 --</p> <p>19 well, 2013 through today -- wholesalers --</p> <p>20 excuse me.</p> <p>21 Let me ask that question again.</p> <p>22 One of the exemptions you're</p> <p>23 referring to is from 2013 up to today,</p> <p>24 wholesalers have not been required to give</p> <p>25 lot number data to pharmacies when the</p>
<p style="text-align: right;">Page 183</p> <p>1 L. Craft</p> <p>2 (Recess taken)</p> <p>3 THE VIDEOGRAPHER: The time is</p> <p>4 12:33.</p> <p>5 This begins media unit four.</p> <p>6 We're back on the record.</p> <p>7 Q. Let's pull up Exhibit 4, which</p> <p>8 is your report, and go to page 21, paragraph</p> <p>9 33.</p> <p>10 Ms. Craft, this section of your</p> <p>11 report deals with the DSCSA, which I</p> <p>12 understand to be the Drug Supply Chain</p> <p>13 Security Act.</p> <p>14 You'd agree that the DSCSA does</p> <p>15 not require tracing from the API</p> <p>16 manufacturer to a finished dose</p> <p>17 manufacturer, right?</p> <p>18 MR. STANOCH: Objection to</p> <p>19 form.</p> <p>20 A. I don't know that -- yeah, I</p> <p>21 hadn't thought about that question, but</p> <p>22 you're correct. It deals with finished dose</p> <p>23 drugs and their circulation supply chain.</p> <p>24 Q. And then -- we can take off 33.</p> <p>25 Let's blow up 34 instead.</p>	<p style="text-align: right;">Page 185</p> <p>1 L. Craft</p> <p>2 wholesaler sells medications directly to the</p> <p>3 pharmacy as long as the wholesaler bought it</p> <p>4 from the manufacturer; is that true?</p> <p>5 A. Yes, there are particular</p> <p>6 labeling conventions. I'm not saying that</p> <p>7 lot information is not supplied. I'm saying</p> <p>8 that the DSCSA has very specific formats in</p> <p>9 which that data should accompany and be</p> <p>10 electronically visible on the product.</p> <p>11 Those conventions are not entirely effective</p> <p>12 under those circumstances that you just</p> <p>13 described.</p> <p>14 Q. And so then just to bring back</p> <p>15 to what I asked, if a wholesaler sells</p> <p>16 medication to a pharmacy, like any time from</p> <p>17 2013 to 2019, that wholesaler was not</p> <p>18 required to transmit the lot number of the</p> <p>19 medication to the pharmacy, was it?</p> <p>20 A. That's correct. That doesn't</p> <p>21 mean they didn't do it. It means they</p> <p>22 weren't required to do it under this law.</p> <p>23 Q. Likewise, pharmacies during the</p> <p>24 same timeframe and even up to the present</p> <p>25 day aren't required to maintain the lot</p>

<p style="text-align: right;">Page 186</p> <p>1 L. Craft</p> <p>2 number for the prescriptions that they</p> <p>3 dispense to consumers, are they?</p> <p>4 A. They're not required to</p> <p>5 specifically link the lot number to the</p> <p>6 individually dispensed prescription. That</p> <p>7 doesn't mean that they don't have lot</p> <p>8 numbers and expiration dates in their</p> <p>9 inventory control systems. It merely means</p> <p>10 that this doesn't print out electronically</p> <p>11 or attach to the individual prescription in</p> <p>12 some cases.</p> <p>13 Q. Well, it's also not going to be</p> <p>14 in the pharmacy claims data, right? Lot</p> <p>15 number?</p> <p>16 A. Well, we saw some cases where</p> <p>17 it was in the data that was produced by</p> <p>18 retailer defendants here, but it is not</p> <p>19 required to be.</p> <p>20 Q. In fact, in the majority of</p> <p>21 cases in the pharmacy information that you</p> <p>22 looked at, there was no lot number</p> <p>23 information in there was there?</p> <p>24 MR. STANOCH: Objection to</p> <p>25 form.</p>	<p style="text-align: right;">Page 188</p> <p>1 L. Craft</p> <p>2 form.</p> <p>3 A lot is not a batch, but go</p> <p>4 ahead, Ms. Craft.</p> <p>5 A. I think those are different</p> <p>6 terms, batch and lot conceptually. If you</p> <p>7 mean that in common English, it's a chunk of</p> <p>8 that product being manufactured under that</p> <p>9 NDC. Then I would agree with your</p> <p>10 characterization.</p> <p>11 Q. To be sure, I was going for the</p> <p>12 common use of the term.</p> <p>13 Is it your contention that to</p> <p>14 identify the class members in this case, lot</p> <p>15 number information isn't needed?</p> <p>16 MR. STANOCH: Objection to</p> <p>17 form.</p> <p>18 A. Yes. As I understand the class</p> <p>19 definition, it is triggered by NDC and not</p> <p>20 lot number.</p> <p>21 Q. Is it your contention that lot</p> <p>22 numbers aren't needed to connect consumer</p> <p>23 and TPP purchases of VCDs with sales of</p> <p>24 those VCDs by wholesalers?</p> <p>25 MR. STANOCH: Objection to</p>
<p style="text-align: right;">Page 187</p> <p>1 L. Craft</p> <p>2 A. That would be fair to say. The</p> <p>3 majority did not include lot number.</p> <p>4 Now, why they didn't include</p> <p>5 it, I don't know. But the majority did not</p> <p>6 include lot number.</p> <p>7 Q. I understand.</p> <p>8 Now, I want to kind of talk</p> <p>9 about the relationship between NDCs and lot</p> <p>10 numbers.</p> <p>11 NDCs are separate from lot</p> <p>12 numbers, right?</p> <p>13 A. A lot number is subsumed within</p> <p>14 or is a subpart of an NDC, which is to say</p> <p>15 they represent different things. The lot</p> <p>16 has to do with a particular duration of</p> <p>17 manufacturers, so a chunk of that NDC being</p> <p>18 manufactured, so --</p> <p>19 Q. Sorry.</p> <p>20 A. No, that's fine. Go ahead.</p> <p>21 Q. I guess just to make sure I</p> <p>22 understand then, a lot is going to be -- a</p> <p>23 lot is maybe equivalent to, like, a batch of</p> <p>24 medication all united under one NDC?</p> <p>25 MR. STANOCH: Objection to</p>	<p style="text-align: right;">Page 189</p> <p>1 L. Craft</p> <p>2 form.</p> <p>3 A. I don't know that that's lot</p> <p>4 number specific. What you're saying is is</p> <p>5 the lot number the indispensable item that</p> <p>6 will tell you where a particular source of</p> <p>7 supply came from, through which wholesaler</p> <p>8 was a particular quantity of the drug</p> <p>9 product obtained and no, lot numbers are not</p> <p>10 necessarily the essential element for doing</p> <p>11 that. There are, of course, purchase and</p> <p>12 supply agreements that exist between</p> <p>13 pharmacies and their sources of supply.</p> <p>14 Q. Without either looking at</p> <p>15 those -- without looking at those</p> <p>16 agreements, how do you propose to know</p> <p>17 whether with respect to the wholesaler</p> <p>18 subclasses a consumer actually purchased</p> <p>19 something that came via a wholesaler to the</p> <p>20 pharmacy?</p> <p>21 A. So I would expect that that</p> <p>22 would depend upon the data and I don't mean</p> <p>23 reading individual contracts, but the supply</p> <p>24 data from the inventory control systems of</p> <p>25 the pharmacies, which, of course, have</p>

<p style="text-align: right;">Page 190</p> <p>1 L. Craft</p> <p>2 inventory control systems that show when</p> <p>3 they're getting low on a particular product</p> <p>4 and need more and that then triggers a</p> <p>5 reordering process. I believe Mr. Kosty</p> <p>6 refers to that in his report.</p> <p>7 Q. And correct me if I'm wrong,</p> <p>8 but I don't think there's any discussion of</p> <p>9 these inventory control systems at</p> <p>10 pharmacies or however you would leverage</p> <p>11 those in your methodology for identifying</p> <p>12 class members, is there?</p> <p>13 A. I don't recall if I mentioned</p> <p>14 inventory control systems. They clearly</p> <p>15 exist. That's, as Mr. Kosty points out, how</p> <p>16 pharmacies decide to reorder and even</p> <p>17 automatically reorder through a wholesaler</p> <p>18 or manufacturer and how their supply is</p> <p>19 tracked.</p> <p>20 And this is because the</p> <p>21 pharmaceutical industry is very, very</p> <p>22 sensitive of the aging of product. We have</p> <p>23 firm expiration dates. We can't sell</p> <p>24 outdated product. Generally speaking, it</p> <p>25 needs to have at least a year of life left</p>	<p style="text-align: right;">Page 192</p> <p>1 L. Craft</p> <p>2 through wholesaler acts, then we know we've</p> <p>3 got wholesaler acts there.</p> <p>4 In other cases, there may be</p> <p>5 multiple sources of the drug and then we</p> <p>6 have to look more closely at the inventory</p> <p>7 levels to see when product arrives from a</p> <p>8 particular wholesaler, remembering we've</p> <p>9 only got three wholesaler defendants, right?</p> <p>10 So the wholesaler defendants</p> <p>11 themselves have records of how much product</p> <p>12 of the NDC they shipped to pharmacies over</p> <p>13 the class period and within particular</p> <p>14 timeframes within the class period.</p> <p>15 Q. Have you ever actually used</p> <p>16 pharmacy information regarding who its prime</p> <p>17 supplier is or wholesaler information about</p> <p>18 who it's supplying to to identify in a set</p> <p>19 of claims data which consumer bought via</p> <p>20 which wholesaler?</p> <p>21 MR. STANOCH: Objection to</p> <p>22 form.</p> <p>23 Go ahead.</p> <p>24 A. No, I have not.</p> <p>25 Q. And then another question that</p>
<p style="text-align: right;">Page 191</p> <p>1 L. Craft</p> <p>2 on it at the time that it is dispensed to</p> <p>3 the consumer. It's essential that those</p> <p>4 inventory control mechanisms be in place.</p> <p>5 Q. So what data then do you</p> <p>6 propose to get and use to determine whether</p> <p>7 or not a consumer falls into one of the</p> <p>8 wholesaler specific subclasses?</p> <p>9 A. Right. Well, in some cases,</p> <p>10 the pharmacy may be able to identify that it</p> <p>11 was exclusively supplied for these</p> <p>12 particular products by one source, one</p> <p>13 wholesaler during the period in question.</p> <p>14 In other cases, they may have</p> <p>15 mixed sources of supply. For example, in</p> <p>16 one period, they may have bought all of</p> <p>17 their product through a prime supplier</p> <p>18 arrangement and in another, they change</p> <p>19 their prime supplier. So in that case, the</p> <p>20 data that simply says "Here are my supply</p> <p>21 arrangements" would be sufficient and we</p> <p>22 could match that to time periods.</p> <p>23 So if a consumer is buying in</p> <p>24 2018 and product has since 2017 been</p> <p>25 acquired by a particular pharmacy only</p>	<p style="text-align: right;">Page 193</p> <p>1 L. Craft</p> <p>2 I had, you had mentioned -- I'll strike</p> <p>3 that. I'll come back to it if I can recall.</p> <p>4 Now, you're aware in this case</p> <p>5 that not all manufacturers initiated a</p> <p>6 recall of all lots of their VCDs, right?</p> <p>7 A. Yes. That's correct. I</p> <p>8 believe I answered that question earlier.</p> <p>9 Q. So I guess to the extent that a</p> <p>10 manufacturer's recall was lot specific as</p> <p>11 opposed to all lots, wouldn't you need to</p> <p>12 know the lot number of the medication that</p> <p>13 was dispensed to actually know if the</p> <p>14 consumer received recalled valsartan?</p> <p>15 MR. STANOCH: Objection.</p> <p>16 Misstates her opinions.</p> <p>17 Incomplete hypothetical.</p> <p>18 A. I wasn't asked to analyze</p> <p>19 whether a consumer received recalled</p> <p>20 product. Manufacturers stage recalls when</p> <p>21 they feel they're ready to stage a recall,</p> <p>22 when they want to. What I tried to explain</p> <p>23 this morning is that I understand the scope</p> <p>24 of the case to be specific to NDCs and not</p> <p>25 merely the portion that was recalled. We</p>

Page 194	Page 196
<p>1 L. Craft</p> <p>2 have years of consumption of these products</p> <p>3 that predates the recall and some of the</p> <p>4 NDCs were entirely sold pre-recall.</p> <p>5 As a result, it is not -- I</p> <p>6 have not examined or attempted to determine</p> <p>7 how one might establish that a consumer got</p> <p>8 a specifically recalled lot.</p> <p>9 Q. Right. Again, just to bring</p> <p>10 you back to what I was asking, you would</p> <p>11 need the lot information to determine if a</p> <p>12 consumer got a lot of recalled product, yes?</p> <p>13 MR. STANOCH: Objection.</p> <p>14 Asked and answered.</p> <p>15 A. If the recall was of a limited</p> <p>16 number of lots -- I mean, of course, let's</p> <p>17 take into account the practical reality that</p> <p>18 recalls routinely say of an expired product.</p> <p>19 Right? So if the dating of the prescription</p> <p>20 is such that it would have been expired,</p> <p>21 then we have a different question. But I --</p> <p>22 Q. Understood.</p> <p>23 A. I'm not suggesting that I can</p> <p>24 identify a lot without a lot number.</p> <p>25 Q. I understand. Okay. Okay.</p>	<p>1 L. Craft</p> <p>2 A. You are correct.</p> <p>3 MR. DORNER: My wife will be</p> <p>4 happy that I managed to work her into</p> <p>5 this deposition.</p> <p>6 MR. STANOCH: Congratulations</p> <p>7 on your nuptials, by the way.</p> <p>8 MR. DORNER: Oh, thank you,</p> <p>9 Dave. I actually do appreciate that.</p> <p>10 MR. STANOCH: I know it was</p> <p>11 relatively recent. Relatively. COVID</p> <p>12 time.</p> <p>13 MR. DORNER: Can we go to</p> <p>14 paragraph 45, please? It should be on</p> <p>15 the next page.</p> <p>16 Q. Ms. Craft, in paragraph 45, you</p> <p>17 discuss pharmacy data and you say that</p> <p>18 "Pharmacies collect and retain information</p> <p>19 on each pharmaceutical transaction,</p> <p>20 sufficient to identify any TPP that provided</p> <p>21 payment for the drug."</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>
Page 195	Page 197
<p>1 L. Craft</p> <p>2 Let's move on to page 27 of your report,</p> <p>3 paragraph 43.</p> <p>4 Here, you say that "Pharmacies</p> <p>5 collect and retain information on each</p> <p>6 pharmaceutical transaction sufficient to</p> <p>7 identify the patient for whom the</p> <p>8 prescription is filled and thus, the</p> <p>9 consumer paying in whole or in part for the</p> <p>10 purchase."</p> <p>11 I don't intend to dwell on this</p> <p>12 very long, Ms. Craft. My only question is</p> <p>13 your statement here "and thus the consumer</p> <p>14 paying in whole and in part for the</p> <p>15 purchase," that assumes that the person</p> <p>16 going to the pharmacy and paying for the</p> <p>17 product is actually the person consuming the</p> <p>18 product, right?</p> <p>19 A. Yes. Fair enough.</p> <p>20 Q. Okay. If I go and pick up a</p> <p>21 prescription for my wife and I pay for it</p> <p>22 with my money, it's still going to show her</p> <p>23 name in the claims data?</p> <p>24 MR. STANOCH: Objection to</p> <p>25 form.</p>	<p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>

Page 198

Page 200

L. Craft

I think that was your firm,
actually, who obtained that ruling.

MR. DORNER: I'm not forcing her. If she doesn't know, she can say she doesn't know, Dave.

MR. STANOCH: I'm just stating it's improper to ask a question a third and fourth time requiring a yes or no answer per the rulings of the Special Master that the defendants themselves have obtained in this case.

MR. GOLDBERG: Actually -- this is Seth Goldberg for the record.

You're misstating the ruling and the ruling is that a witness can be asked a yes or no question. They should answer yes or no and if there's any information they need to provide to qualify their answer, they could do that.

MR. STANOCH: Very well.

Same objections: Lacks foundation.

Asked and answered.

Page 199

Page 201

L. Craft

Q. Okay.

So that's a yes to my question?

MR. STANOCH: Objection again.

Asked and answered a third
e.

Presumes facts not in evidence.

Lacks foundation.

Misstates her prior testimony.

A. I'm sorry. Is there a question on the floor?

Q. Yeah, I just asked if that's a yes to my question, Mr. Stanoch noted his objection.

MR. STANOCH: Same objection.

I believe Special Master

Vanaskie has indicated that witnesses cannot be forced to answer yes or no.

L. Craft

Assumes facts not in evidence.

Misstates prior testimony.

The witness has already
qualified her answer multiple times.

If you'd like to say it a fourth time, Ms. Craft, go ahead.

MR. DORNER: Can we go to --

let's pull up Exhibit M, which we will mark as Exhibit 7. Let's go ahead and go to page 60 of this PDF.

(Whereupon, Exhibit 7 was marked for identification.)

Q. All right, Ms. Craft.
I want to look at your

<p style="text-align: right;">Page 202</p> <p>1 L. Craft</p> <p>2 definition here, the Wholesaler Defendants</p> <p>3 Unjust Enrichment Claim, specifically</p> <p>4 the column dedicated to definition.</p> <p>5 You've defined one of the</p> <p>6 wholesaler defendant subclasses as -- well,</p> <p>7 it's reflected in the third column of</p> <p>8 Exhibit 7 on page 50, right?</p> <p>9 MR. STANOCH: Objection to</p> <p>10 form.</p> <p>11 Q. You don't need to read the</p> <p>12 whole thing --</p> <p>13 MR. STANOCH: Objection to</p> <p>14 form.</p> <p>15 Mischaracterizes the document,</p> <p>16 that she defined anything.</p> <p>17 A. I'm sorry, Mr. Dorner. I</p> <p>18 just -- I needed a second to get this</p> <p>19 document up on my screen and --</p> <p>20 Q. No problem and I think I can</p> <p>21 restate it so that way it addresses</p> <p>22 Mr. Stanoch's objection.</p> <p>23 The third column from the left</p> <p>24 on page 60 of Exhibit 7 sets forth the</p> <p>25 definition in this case for one of the</p>	<p style="text-align: right;">Page 204</p> <p>1 L. Craft</p> <p>2 distributor.</p> <p>3 Q. And then likewise if that</p> <p>4 consumer, say, purchased from -- purchased</p> <p>5 VCDs that the pharmacy obtained directly</p> <p>6 from a manufacturer or from a different</p> <p>7 wholesaler, to the extent there are any,</p> <p>8 that person would also not fall within this</p> <p>9 subclass, right?</p> <p>10 MR. STANOCH: Objection to</p> <p>11 form.</p> <p>12 A. It's my understanding they</p> <p>13 would not be part of this unjust enrichment</p> <p>14 claim against the wholesalers, but of course</p> <p>15 they would simultaneously be part of other</p> <p>16 subclasses based on the manufacturer or API</p> <p>17 supplier of the product or the retail</p> <p>18 pharmacy at which they bought the product.</p> <p>19 So in terms of ascertaining class</p> <p>20 membership, there are a number of subclasses</p> <p>21 here. It's true.</p> <p>22 Q. Then for the wholesaler</p> <p>23 subclasses that relate to third-party payors</p> <p>24 as opposed to individual consumers, it would</p> <p>25 be the same situation?</p>
<p style="text-align: right;">Page 203</p> <p>1 L. Craft</p> <p>2 wholesaler defendants unjust enrichment</p> <p>3 subclasses.</p> <p>4 Fair enough?</p> <p>5 A. Yes, I would agree with your</p> <p>6 characterization.</p> <p>7 MR. DORNER: You caught me on</p> <p>8 that one, Dave. I agree with you.</p> <p>9 Q. If you need to take the time to</p> <p>10 read this definition, go right ahead.</p> <p>11 My questions, I think, are</p> <p>12 going to be fairly simple.</p> <p>13 Would you agree that to fall</p> <p>14 within this definition of the class you</p> <p>15 would identify an individual must have</p> <p>16 purchased VCDs that were either distributed</p> <p>17 by Cardinal Health, McKesson or Amerisource</p> <p>18 Bergen?</p> <p>19 MR. STANOCH: Objection to</p> <p>20 form.</p> <p>21 Misstates the document, but go</p> <p>22 ahead.</p> <p>23 A. Yes, that's my understanding,</p> <p>24 that an element of this particular subclass</p> <p>25 is the identity of the wholesale</p>	<p style="text-align: right;">Page 205</p> <p>1 L. Craft</p> <p>2 What I mean by that is if they</p> <p>3 didn't buy or -- excuse me -- pay for</p> <p>4 product that wasn't provided by one of the</p> <p>5 three wholesaler defendants to the pharmacy,</p> <p>6 then those TPPs would not fall within their</p> <p>7 subclass against wholesalers; is that right?</p> <p>8 MR. STANOCH: Objection to</p> <p>9 form.</p> <p>10 Go ahead.</p> <p>11 A. Yes, I believe the claims</p> <p>12 against the wholesalers are limited to the</p> <p>13 product they actually supplied.</p> <p>14 Q. I want to turn to a different</p> <p>15 portion of your report. This is going to be</p> <p>16 page 32, paragraph 51. Thank you for</p> <p>17 blowing that up.</p> <p>18 Paragraph 51 is a portion of</p> <p>19 your report that relates to the medical</p> <p>20 monitoring classes.</p> <p>21 I want to focus on the third</p> <p>22 sentence -- fourth sentence which says "This</p> <p>23 makes it possible to construct a consumption</p> <p>24 record for individual consumers and the</p> <p>25 reason for that is because the NDC dosage</p>

<p style="text-align: right;">Page 206</p> <p>1 L. Craft</p> <p>2 strength quantity dispensed and dates of</p> <p>3 each dispense are reported."</p> <p>4 That's in the preceding</p> <p>5 sentence. Do you see where I'm referring</p> <p>6 to, Ms. Craft?</p> <p>7 A. I do.</p> <p>8 Q. Okay.</p> <p>9 Are you familiar -- let me back</p> <p>10 up.</p> <p>11 I don't see it used in this</p> <p>12 paragraph, so let me ask if you're familiar</p> <p>13 generally with the term in this case of</p> <p>14 "lifetime cumulative threshold."</p> <p>15 Is that a term you're familiar</p> <p>16 with?</p> <p>17 A. Yes.</p> <p>18 Q. Are you familiar with how</p> <p>19 the -- and I might say LCT.</p> <p>20 Is that okay?</p> <p>21 A. Sure.</p> <p>22 Q. All right. Great.</p> <p>23 Are you familiar with how the</p> <p>24 LCT thresholds were calculated in this case?</p> <p>25 MR. STANOCH: Objection to</p>	<p style="text-align: right;">Page 208</p> <p>1 L. Craft</p> <p>2 Again, just making these</p> <p>3 numbers up. Okay?</p> <p>4 MR. STANOCH: Objection to</p> <p>5 form.</p> <p>6 Incomplete hypothetical.</p> <p>7 Q. Do you have an understanding of</p> <p>8 how those specific numbers, the three</p> <p>9 months, the 150 milligrams, how those</p> <p>10 numbers were arrived at in determining what</p> <p>11 the various lifetime cumulative threshold</p> <p>12 would be?</p> <p>13 MR. STANOCH: Objection again.</p> <p>14 Incomplete hypothetical.</p> <p>15 Caution the witness not to</p> <p>16 divulge any information from privileged</p> <p>17 communications.</p> <p>18 A. I certainly was not involved in</p> <p>19 any discussions about or in the process of</p> <p>20 defining what the thresholds should be. I</p> <p>21 merely make the point here that those</p> <p>22 thresholds are functionally defined based on</p> <p>23 an observable quantity about which we need</p> <p>24 have no speculation whatsoever, which is the</p> <p>25 number of milligrams of a specific product</p>
<p style="text-align: right;">Page 207</p> <p>1 L. Craft</p> <p>2 form.</p> <p>3 Vague and ambiguous.</p> <p>4 Caution the witness to the</p> <p>5 extent she has any information that</p> <p>6 would be subject to privilege.</p> <p>7 A. It's my understanding that</p> <p>8 the -- there's a functional definition here</p> <p>9 that looks to be total quantity consumed of</p> <p>10 VCDs by a consumer over the class period and</p> <p>11 that that quantity is a function of the</p> <p>12 dosage strength that is dispensed together</p> <p>13 with the quantity that is dispensed so that</p> <p>14 this is linked to the NDCs, that it</p> <p>15 specifies quantity of product dispensed as</p> <p>16 opposed to some other quantity metric to</p> <p>17 that particular consumer.</p> <p>18 Q. And I guess -- and I'm not</p> <p>19 saying you didn't answer my question here,</p> <p>20 but let me ask it a slightly different way.</p> <p>21 I can't tell you the lifetime</p> <p>22 cumulative thresholds in this case off the</p> <p>23 top of my head, but say hypothetically that</p> <p>24 it's, you know, three months' worth of 150</p> <p>25 milligram valsartan produced by Hetero Labs.</p>	<p style="text-align: right;">Page 209</p> <p>1 L. Craft</p> <p>2 added up over time for a given consumer and</p> <p>3 combined across products.</p> <p>4 Q. Okay. All right. I</p> <p>5 understand. I thank you for your</p> <p>6 clarification.</p> <p>7 Isn't the purpose of the</p> <p>8 lifetime cumulative threshold to determine</p> <p>9 how much NDMA or NDEA a person allegedly</p> <p>10 ingested over the claims period?</p> <p>11 MR. STANOCH: Objection to</p> <p>12 form.</p> <p>13 A. It's not to me to define why</p> <p>14 that threshold is being created. I'm just</p> <p>15 saying it's one you could implement in terms</p> <p>16 of ascertaining class membership. How that</p> <p>17 will be used in the proof of increased</p> <p>18 cancer risk is not a topic for me to</p> <p>19 address.</p> <p>20 Q. So I guess let me ask you this</p> <p>21 then: For each given NDC, at-issue NDC --</p> <p>22 excuse me.</p> <p>23 For each given at-issue NDC,</p> <p>24 you would agree that the amount of NDMA or</p> <p>25 NDEA varied across the lots and the</p>

<p style="text-align: right;">Page 210</p> <p>1 L. Craft</p> <p>2 individual pills and the individual</p> <p>3 prescriptions, even under the same NDC,</p> <p>4 right?</p> <p>5 MR. STANOCH: Objection to</p> <p>6 form.</p> <p>7 Lacks foundation.</p> <p>8 Facts not in evidence.</p> <p>9 Outside the scope.</p> <p>10 Vague.</p> <p>11 Go ahead.</p> <p>12 A. I wouldn't agree because I have</p> <p>13 no opinion about variation in those levels</p> <p>14 of contamination in the individual products.</p> <p>15 That's beyond the scope of my report and my</p> <p>16 expertise.</p> <p>17 Q. Okay.</p> <p>18 You did review the economic</p> <p>19 loss complaint in this case, right?</p> <p>20 A. Yes, I did.</p> <p>21 Q. I believe the economic loss</p> <p>22 complaint makes allegations of various</p> <p>23 ranges of NDMA or NDEA impurities in VCDs.</p> <p>24 So I guess I want to assume that for</p> <p>25 purposes of this question that there was</p>	<p style="text-align: right;">Page 212</p> <p>1 L. Craft</p> <p>2 Incomplete hypothetical.</p> <p>3 Misstates the document.</p> <p>4 I'm not even sure which</p> <p>5 complaint we're talking about.</p> <p>6 Vague and ambiguous.</p> <p>7 Outside the scope.</p> <p>8 A. I suppose that the answer to</p> <p>9 that question is it depends on how</p> <p>10 absolutely precise you need to get to a</p> <p>11 specific of NDMA or whatever the substance</p> <p>12 may be and, you know, it is not uncommon in</p> <p>13 all forms of a large transaction litigation</p> <p>14 that we may have to make some estimates</p> <p>15 based on averages over periods of time,</p> <p>16 products, whatever it may be.</p> <p>17 What you are asking is if I</p> <p>18 want to know the exact amount of these</p> <p>19 contaminants that were ingested by a</p> <p>20 customer and you asked me to assume that</p> <p>21 there was variation among the prescriptions.</p> <p>22 Then if you need a precise, precise</p> <p>23 estimate, then yes, it would be useful to</p> <p>24 know the exact level of contaminants in each</p> <p>25 pill that was ingested by the consumer.</p>
<p style="text-align: right;">Page 211</p> <p>1 L. Craft</p> <p>2 variation in the various lots produced under</p> <p>3 the same NDC.</p> <p>4 Okay?</p> <p>5 MR. STANOCH: Objection.</p> <p>6 I've lost the thread there.</p> <p>7 Unintelligible.</p> <p>8 Go ahead, if you could answer.</p> <p>9 A. Well, I don't think I have a</p> <p>10 question yet, but I understand your</p> <p>11 assumption. You're asking me to assume</p> <p>12 there was variation in the concentration of</p> <p>13 these contaminants by lot number.</p> <p>14 Q. I think you nailed it.</p> <p>15 A. But what's the question? You</p> <p>16 told me to assume that.</p> <p>17 Q. Sure. So my question is -- if</p> <p>18 the amount of NDMA or NDEA in lots, if any,</p> <p>19 differed, wouldn't you at least need to have</p> <p>20 the lot information of the VCDs that the</p> <p>21 consumer obtained to determine that</p> <p>22 consumer's actual consumption of NDMA or</p> <p>23 NDEA?</p> <p>24 MR. STANOCH: Objection to</p> <p>25 form.</p>	<p style="text-align: right;">Page 213</p> <p>1 L. Craft</p> <p>2 But, you know, there's not a</p> <p>3 great deal of litigation that is undertaken</p> <p>4 at that level of precision and I don't know</p> <p>5 what the statistical methods are that are</p> <p>6 being applied in this case to estimate the</p> <p>7 exposure levels that are associated with a</p> <p>8 30-day supply of a particular NDC and I</p> <p>9 can't comment on their levels of precision</p> <p>10 or their statistical variation.</p> <p>11 Q. You mentioned to get a very</p> <p>12 precise estimate and I appreciate that.</p> <p>13 Even by its nature, even if</p> <p>14 you're trying to do an estimate of how much</p> <p>15 NDMA or NDEA someone might have consumed, if</p> <p>16 the various lots under a single NDC had</p> <p>17 variable amounts of NDMA or NDEA in them,</p> <p>18 that would even affect the accuracy of your</p> <p>19 estimate, wouldn't it?</p> <p>20 MR. STANOCH: Objection to</p> <p>21 form.</p> <p>22 Asked and answered.</p> <p>23 Incomplete hypothetical.</p> <p>24 Lacks foundation.</p> <p>25 Vague and ambiguous.</p>

<p style="text-align: right;">Page 214</p> <p>1 L. Craft</p> <p>2 Compound.</p> <p>3 Go ahead, if you understand.</p> <p>4 A. I do. It's not a question I</p> <p>5 could answer because I'm being asked here to</p> <p>6 provide an opinion about the reasonableness</p> <p>7 of combining lots in order to derive an</p> <p>8 estimate of exposure for a given NDC and I</p> <p>9 have not analyzed that subject. That is not</p> <p>10 within the scope of my report. That's</p> <p>11 somebody else's outlook and I really can't</p> <p>12 opine about it. That might be a perfectly</p> <p>13 reasonable procedure to use, but that's -- I</p> <p>14 haven't attempted to assess that and won't.</p> <p>15 Q. Now, claims data -- be it PBM</p> <p>16 or pharmacy-provided claims data -- don't</p> <p>17 show whether the proposed class members</p> <p>18 actually took their medication, do they?</p> <p>19 MR. STANOCH: Objection to</p> <p>20 form.</p> <p>21 Vague.</p> <p>22 A. Of course not. Nor does any of</p> <p>23 the scientific literature that addresses</p> <p>24 adherence or compliance or thresholds</p> <p>25 actually used in the estimation procedure</p>	<p style="text-align: right;">Page 216</p> <p>1 L. Craft</p> <p>2 course that's the kind of thing that could</p> <p>3 be easily validated in claim form by not</p> <p>4 only purchased, but consumed XYZ.</p> <p>5 So I'm telling you the science</p> <p>6 in this area about drug compliance and</p> <p>7 consumption is routinely oriented this way.</p> <p>8 It makes the functional assumption that</p> <p>9 prescribing results in complete consumption.</p> <p>10 It is a limitation because there is a</p> <p>11 possibility that someone bought their drugs,</p> <p>12 took them home and didn't consume them and</p> <p>13 that's a possibility that one could address</p> <p>14 through a claim form, I would assume. So it</p> <p>15 is not -- so I still treat this just as the</p> <p>16 chain article would. I treat dispensing as</p> <p>17 a proxy for consumption.</p> <p>18 Q. To be clear, you are not</p> <p>19 proposing using a claim form to determine</p> <p>20 actual consumption in order to identify</p> <p>21 class members, are you?</p> <p>22 MR. STANOCH: Objection.</p> <p>23 Misstates testimony.</p> <p>24 A. I'm just suggesting that one</p> <p>25 way to deal with this is if you want your</p>
<p style="text-align: right;">Page 215</p> <p>1 L. Craft</p> <p>2 individual consumption. Data in this</p> <p>3 area -- studies, good academic studies,</p> <p>4 including the Chang study that is cited and</p> <p>5 relied upon by Mr. Kosty -- use</p> <p>6 prescriptions dispensed, drugs that went</p> <p>7 home with the consumer and they operate from</p> <p>8 an assumption that the consumer didn't pay</p> <p>9 for the drugs and then throw them in the</p> <p>10 garbage, but, in fact, consumed the drugs.</p> <p>11 Q. So then if we look back --</p> <p>12 actually, stay in paragraph 51.</p> <p>13 Wouldn't it be more accurate</p> <p>14 instead of calling it a consumption record,</p> <p>15 you could say with certainty if you instead</p> <p>16 tout it as a dispensing record, right?</p> <p>17 MR. STANOCH: Objection to</p> <p>18 form.</p> <p>19 I guess incomplete hypothetical</p> <p>20 in terms of writing report, but go</p> <p>21 ahead.</p> <p>22 A. To treat that record as a</p> <p>23 consumption record, one is operating under</p> <p>24 the assumption that the consumer actually</p> <p>25 ingested the product that they bought and of</p>	<p style="text-align: right;">Page 217</p> <p>1 L. Craft</p> <p>2 consumer class members in the medical</p> <p>3 monitoring class to attest to the fact that</p> <p>4 they did, in fact, consume what they bought,</p> <p>5 you could always do that when they submit</p> <p>6 their claims at the conclusion of the case.</p> <p>7 Q. Now, have you ever in the past</p> <p>8 in any case -- have you ever used claims</p> <p>9 data, either from a pharmacy or a PBM, in</p> <p>10 the past to determine the quantity of</p> <p>11 product, either dispensed or consumed by</p> <p>12 NDC?</p> <p>13 MR. STANOCH: Objection to</p> <p>14 form.</p> <p>15 That's really compound in terms</p> <p>16 of dispensed or consumed, Mr. Dorner,</p> <p>17 if you'd like to break it up maybe.</p> <p>18 But it's your question.</p> <p>19 Objection. Form.</p> <p>20 MR. DORNER: Sure. To be</p> <p>21 clear, I was just trying to -- we just</p> <p>22 had a discussion about consumption</p> <p>23 versus dispensing, so I'll say -- I'll</p> <p>24 say consumption in this case.</p> <p>25 Q. So in the past, in a case, have</p>

<p style="text-align: right;">Page 218</p> <p>1 L. Craft</p> <p>2 you ever used NDC information either from</p> <p>3 pharmacy or PBM data to construct a list of</p> <p>4 class members and their amount of product</p> <p>5 consumed?</p> <p>6 MR. STANOCH: Just caution the</p> <p>7 witness not to divulge information</p> <p>8 subject to a confidentiality order or a</p> <p>9 consulting arrangement, if any.</p> <p>10 Just go ahead and answer.</p> <p>11 A. Not on an order to prepare a</p> <p>12 list, but in a number of antitrust cases in</p> <p>13 which I've worked, the class definition</p> <p>14 itself asks that we differentiate between</p> <p>15 consumers who switched, for example, to a</p> <p>16 generic product, when it became available</p> <p>17 and analyzed whether they persisted on that</p> <p>18 generic product.</p> <p>19 So in other words, how long did</p> <p>20 they continue taking it, how many</p> <p>21 prescriptions, identify when that switch was</p> <p>22 made, compare it to earlier purchases of the</p> <p>23 brand product.</p> <p>24 It is quite common to have to</p> <p>25 analyze individual class member purchases</p>	<p style="text-align: right;">Page 220</p> <p>1 L. Craft</p> <p>2 Let's go ahead and move on to</p> <p>3 page 34, paragraph 54 of your report in</p> <p>4 Exhibit 4. Okay?</p> <p>5 In this paragraph, you're</p> <p>6 describing what you call standard exclusions</p> <p>7 common to almost all end payor class actions</p> <p>8 and one of those two standard exclusions</p> <p>9 deals with the defendants and their</p> <p>10 affiliated entities and personnel and</p> <p>11 defendants assignments and successors -- I</p> <p>12 guess that's two to them -- and I believe</p> <p>13 your proposal is that the defendants can</p> <p>14 provide a list of those in the first two</p> <p>15 categories.</p> <p>16 Is that -- am I understanding</p> <p>17 your position correctly?</p> <p>18 A. So yes, although I want to add</p> <p>19 the proviso that in number one, my general</p> <p>20 statement here was not only about entities</p> <p>21 but about personnel and we should talk about</p> <p>22 those separately because an affiliated</p> <p>23 entity is a comparatively small number of</p> <p>24 operations and those operations are only</p> <p>25 third-party payors who might have claims if</p>
<p style="text-align: right;">Page 219</p> <p>1 L. Craft</p> <p>2 for -- to meet the contours of class</p> <p>3 definitions when we're talking about</p> <p>4 alternative products, switching between</p> <p>5 generics and between -- between generics and</p> <p>6 brands most typically.</p> <p>7 So that is not precisely what</p> <p>8 you're saying, but it is an analogous</p> <p>9 exercise that is carried out by looking at</p> <p>10 records across time for consumers.</p> <p>11 Q. In the antitrust context,</p> <p>12 though, whether or not the medication was</p> <p>13 consumed or how much of an impurity, if any,</p> <p>14 that a consumer consumed, that is not a</p> <p>15 factor in an antitrust case, is it?</p> <p>16 A. That's correct. You're right.</p> <p>17 I took -- I'm sorry. Let me just clarify.</p> <p>18 I took your question to refer to my personal</p> <p>19 experience with tracking individual consumer</p> <p>20 purchases across time and being able to</p> <p>21 collect them on an individual level and I'm</p> <p>22 merely making the point that that's</p> <p>23 certainly something I've done numerous</p> <p>24 times.</p> <p>25 Q. I appreciate the clarification.</p>	<p style="text-align: right;">Page 221</p> <p>1 L. Craft</p> <p>2 they had self-funded health plans.</p> <p>3 So if they had self-funded</p> <p>4 health plans, the defendants can say so.</p> <p>5 They can say I've got this affiliate and</p> <p>6 that affiliate and this other affiliate with</p> <p>7 self-funded health plans and then one would</p> <p>8 simply programmatically exclude TPP claims</p> <p>9 under those health plans.</p> <p>10 Doing that also, of course,</p> <p>11 links the individual employee purchases</p> <p>12 under those health plans. So the -- because</p> <p>13 the health plan links to the member ID, then</p> <p>14 we can -- without the defendants giving us a</p> <p>15 list of their employees' names, but instead</p> <p>16 giving us a list of their self-funded health</p> <p>17 plans, we can make this determination. That</p> <p>18 was for one.</p> <p>19 You also asked about</p> <p>20 assignments and successors, which I would</p> <p>21 treat the same as affiliated entities there.</p> <p>22 Q. Okay.</p> <p>23 I guess I want to focus then</p> <p>24 instead on personnel and personnel who are</p> <p>25 not members of a self-funded plan by one of</p>

Page 222

1 L. Craft

2 the defendants and their affiliates or

3 assignments or successors.

4 Okay?

5 MR. STANOCH: Objection.

6 Go ahead.

7 A. For example, an employee who is

8 a cash purchaser? Is that what you're

9 thinking of?

10 Q. That's one example, yes. Or an

11 employee who -- just any employee who has a

12 co-pay and who doesn't have a co-pay

13 associated with a self-insured plan but

14 rather a fully insured plan.

15 Fair enough?

16 A. Yes. So what is your question?

17 Q. So I guess my question is, you

18 know, your report merely says that the

19 defendants can provide a list of their

20 personnel. So I don't actually see a

21 methodology as to how you would use that

22 list, so my question is how do you use that

23 list?

24 MR. STANOCH: Objection to

25 form.

Page 223

1 L. Craft

2 Mischaracterizes the report and

3 the opinion.

4 A. So let me then provide you with

5 further detail, which will hopefully clarify

6 this subject.

7 Defendants identify all their

8 affiliated entities, assignees and

9 successors. That's step one. Step two,

10 those defendants have those affiliated

11 entities and assignees and successors

12 identify their health plans. Obviously, the

13 defendants are not going to have a claim

14 unless they're self-funding those benefits.

15 So they won't be a TPP, so we don't have to

16 worry about that. But we get a complete

17 list of their health plans.

18 Those health plans can then be

19 used to identify personnel, i.e.

20 individuals, within PBM claims data because

21 we'll say health plan, you know, ABC was

22 processed and adjudicated by Express Scripts

23 and so we are going to eliminate the claims

24 of consumers under that health plan.

25 So the presumption there, which

Page 224

1 L. Craft

2 is a simplifying assumption, is that if the

3 individual is covered by that company's

4 health plan, then it is an excluded person

5 in this description.

6 Now, this is a pretty bare

7 bones description and there are a number of

8 ways that one could go about doing this.

9 That leaves you only with the residual

10 problem -- okay? -- but what if -- so all of

11 that is done without the need for a list of

12 employees. You don't have to do any name

13 matching, you don't need a list of

14 employees, you just work backward from the

15 health plan.

16 This leaves you with the

17 possible exception that you've got an

18 employee who, for example, doesn't get

19 health benefits, isn't covered or for some

20 other reason goes in and pays cash without

21 processing through that health plan. In

22 theory, without a list of employees, you're

23 not going to spot that rogue individual who

24 is going in and buying for cash.

25 Once again, it doesn't strike

Page 225

1 L. Craft

2 me as a difficult thing when and if claims

3 are ultimately processed at the outcome of

4 this case to have the claim forms say "I was

5 not at that time an employee of any of the

6 following."

7 These are not going to be

8 material numbers. I'm telling you. That

9 will be cash purchasers while employed by a

10 defendant.

11 Q. Let me pose -- sorry. Go

12 ahead.

13 A. No, no. I'm done.

14 Q. Okay. Let me pose a different

15 hypothetical.

16 Let's say that my firm, Duane

17 Morris, was a defendant in this case. It's

18 not, but let's say it was. Let's say

19 further that I, a Duane Morris employee,

20 purchased valsartan -- at-issue valsartan --

21 during the claims period, between 2012 and

22 the date of the final recall. I'll

23 represent to you -- because this is true --

24 that I am not on Duane Morris's health care

25 plan. I'm on my wife's health care plan.

<p style="text-align: right;">Page 226</p> <p>1 L. Craft</p> <p>2 How does your methodology of</p> <p>3 using the defendant's health care plan data</p> <p>4 account for spouses, dependents and others</p> <p>5 who may be on, you know, their spouse's</p> <p>6 plan?</p> <p>7 MR. STANOCH: Objection to</p> <p>8 form.</p> <p>9 Incomplete hypothetical.</p> <p>10 Vague.</p> <p>11 Ambiguous.</p> <p>12 Compound.</p> <p>13 Go ahead, Ms. Craft.</p> <p>14 A. So short answer, it doesn't.</p> <p>15 And so if one of defendants' employees who</p> <p>16 is not covered by defendant but instead is</p> <p>17 covered by some other insurance makes a</p> <p>18 purchase, the process that I described,</p> <p>19 which doesn't require a list of employees,</p> <p>20 is not going to catch that individual, which</p> <p>21 is the reason why you might want to have</p> <p>22 some statement on an ultimate claim form</p> <p>23 that says I wasn't an employee at the time.</p> <p>24 I mean, I'm just dealing with</p> <p>25 the class definition as I understand it to</p>	<p style="text-align: right;">Page 228</p> <p>1 L. Craft</p> <p>2 claims out.</p> <p>3 Q. And then did you also take out</p> <p>4 individuals associated with those plans from</p> <p>5 any consumer class?</p> <p>6 A. We took out all of the plans</p> <p>7 claims data. I mean, it's --</p> <p>8 Q. I guess I'm not understanding</p> <p>9 what you mean.</p> <p>10 A. Well, the claims --</p> <p>11 MR. STANOCH: Wait. I'm sorry,</p> <p>12 Mr. Dorner. What's the question? I'm</p> <p>13 not understanding what you mean and</p> <p>14 that's not a question. You put a</p> <p>15 question to her. That's all I'm</p> <p>16 saying.</p> <p>17 MR. DORNER: Okay. Well, it</p> <p>18 sounded like she had an explanation, so</p> <p>19 let's let Ms. Craft say what it was.</p> <p>20 MR. STANOCH: Objection to</p> <p>21 form.</p> <p>22 No question.</p> <p>23 Ms. Craft, if you think you can</p> <p>24 answer something in what he asked, go</p> <p>25 ahead.</p>
<p style="text-align: right;">Page 227</p> <p>1 L. Craft</p> <p>2 be currently drafted, but this could easily</p> <p>3 be combined to and personnel who made</p> <p>4 purchases under health plans provided by</p> <p>5 that entity or health coverage provided by</p> <p>6 that entity and then this problem goes away.</p> <p>7 It is -- I mean, there will be some small</p> <p>8 amount of persons who would fall within this</p> <p>9 bucket for precisely the reason that you</p> <p>10 just described. They're not using the</p> <p>11 defendant's health coverage, but they are an</p> <p>12 employee of the defendant and without a list</p> <p>13 of individuals, you won't find them.</p> <p>14 Q. I want to go back to the first</p> <p>15 process you talked about with respect to</p> <p>16 using a defendant's health care plan</p> <p>17 information to -- I think you said</p> <p>18 programmatically exclude employees of that</p> <p>19 defendant.</p> <p>20 Have you ever actually done</p> <p>21 that in producing a list of class members?</p> <p>22 A. Well, I've certainly done that</p> <p>23 in antitrust cases, identifying plans that</p> <p>24 are sponsored by defendants and knocking</p> <p>25 them out of the claims data, taking those</p>	<p style="text-align: right;">Page 229</p> <p>1 L. Craft</p> <p>2 A. When you eliminate all claims</p> <p>3 associated with a particular health plan,</p> <p>4 you eliminate the consumer portion as well</p> <p>5 as the TPP portion because the claim is a</p> <p>6 single unit that is then decomposed into</p> <p>7 those portions.</p> <p>8 Now, can I separately identify</p> <p>9 the TPP and the consumer? Yes. But I'm</p> <p>10 telling you that in the past, when I've been</p> <p>11 asked to remove defendant health plans, it</p> <p>12 has been for the purpose of removing all</p> <p>13 claims under those plans, including consumer</p> <p>14 portions. That's all.</p> <p>15 Q. Okay.</p> <p>16 A. Once again, this data can be</p> <p>17 used to eliminate the consumer, it can be</p> <p>18 used to eliminate the TPP, it can be used to</p> <p>19 eliminate both. It's a question -- I'm</p> <p>20 doing a little rough interpretation of what</p> <p>21 these seven words mean, defendants and their</p> <p>22 affiliated entities and personnel.</p> <p>23 Q. Sure. Okay.</p> <p>24 Now, second -- for those who,</p> <p>25 as we discussed, for whatever reason aren't</p>

<p style="text-align: right;">Page 230</p> <p>1 L. Craft</p> <p>2 on the employer's health care or are cash</p> <p>3 paying, have you ever actually obtained a</p> <p>4 list of individuals from each defendant and</p> <p>5 then removed them somehow from a list of</p> <p>6 potential class members?</p> <p>7 MR. STANOCH: Objection to</p> <p>8 form.</p> <p>9 A. No, I have not. It has been my</p> <p>10 experience that just as the court wouldn't</p> <p>11 expect you to search records to see if the</p> <p>12 judge, the magistrate, the court clerk,</p> <p>13 their family members had claims, that it</p> <p>14 would routinely be the case that one would</p> <p>15 rely on a claim filing that says I'm not one</p> <p>16 of those excluded persons at the end of the</p> <p>17 case, that this is not an issue that is</p> <p>18 routinely tackled prior to a settlement or</p> <p>19 favorable judgment.</p> <p>20 Q. If a person -- strike that.</p> <p>21 Under your methodology for</p> <p>22 identifying defendants' employees, if a</p> <p>23 person worked for a defendant for some but</p> <p>24 not all of the claims period and paid for a</p> <p>25 VCD at issue during a time when he was not</p>	<p style="text-align: right;">Page 232</p> <p>1 L. Craft</p> <p>2 MR. STANOCH: Are you okay with</p> <p>3 that, Ms. Craft?</p> <p>4 THE WITNESS: I will</p> <p>5 accommodate. I'm ready -- I'm happy to</p> <p>6 switch topics, too, I don't mind that.</p> <p>7 But if you need a five-minute break,</p> <p>8 that's fine.</p> <p>9 MR. STANOCH: Let's take a</p> <p>10 break.</p> <p>11 MR. DORNER: Great.</p> <p>12 THE VIDEOGRAPHER: The time is</p> <p>13 12:35.</p> <p>14 This ends media four.</p> <p>15 We're going off the record.</p> <p>16 (Recess taken)</p> <p>17 THE VIDEOGRAPHER: The time is</p> <p>18 1:45.</p> <p>19 This begins media unit five.</p> <p>20 We're back on the record.</p> <p>21 (Whereupon, Exhibit 8 was marked for</p> <p>22 identification.)</p> <p>23 Q. All right.</p> <p>24 Can we go ahead and pull up --</p> <p>25 this will be the exhibit pre-labeled G as in</p>
<p style="text-align: right;">Page 231</p> <p>1 L. Craft</p> <p>2 working for a defendant, would that person</p> <p>3 be included within the class?</p> <p>4 MR. STANOCH: Objection to</p> <p>5 form.</p> <p>6 Incomplete hypothetical.</p> <p>7 A. The answer is I would need</p> <p>8 instructions on which of those was true from</p> <p>9 counsel. I have presently in front of me</p> <p>10 these four exclusions which you read here.</p> <p>11 So what you're saying is would -- how should</p> <p>12 I interpret number one? Should I interpret</p> <p>13 it to mean all purchases by that individual</p> <p>14 or only those made during periods of</p> <p>15 employment? Should I interpret it to mean</p> <p>16 only those purchases made during periods of</p> <p>17 employment when there were health benefits</p> <p>18 that were being used to make the purchase?</p> <p>19 And the answer is I would need clarification</p> <p>20 as to which of those rule sets to apply</p> <p>21 before being able to do it.</p> <p>22 MR. DORNER: We've been going</p> <p>23 for about an hour and I'm at a point</p> <p>24 where I was going to switch gears, so I</p> <p>25 suggest we take five.</p>	<p style="text-align: right;">Page 233</p> <p>1 L. Craft</p> <p>2 golf. We'll mark this as Exhibit 8. This</p> <p>3 is an Excel spreadsheet we received from you</p> <p>4 as part of your production. It's a list of</p> <p>5 third-party payors and associated plans with</p> <p>6 those third-party payors.</p> <p>7 Is that an accurate</p> <p>8 characterization?</p> <p>9 A. Yes. That's correct.</p> <p>10 Q. This list is all drawn from</p> <p>11 IQVIA Xponent data, right?</p> <p>12 A. That's correct.</p> <p>13 Q. Let me ask just generally what</p> <p>14 was the purpose of developing this list?</p> <p>15 A. To determine whether the TPP</p> <p>16 class was numerous.</p> <p>17 Q. Okay.</p> <p>18 So your list goes to your</p> <p>19 numerosity opinion?</p> <p>20 A. Correct.</p> <p>21 Q. Okay.</p> <p>22 When you were preparing this</p> <p>23 list, did you attempt to apply any of the</p> <p>24 proposed class exclusions to the entities</p> <p>25 that, you know, I guess appeared in the</p>

<p style="text-align: right;">Page 234</p> <p>1 L. Craft</p> <p>2 IQVIA data and may have wound up in this</p> <p>3 list?</p> <p>4 A. Yes. I removed federal</p> <p>5 government entities from this list and I</p> <p>6 further removed the portion of Medicare --</p> <p>7 sorry -- Medicaid claims which are paid</p> <p>8 directly by the state. So traditional</p> <p>9 Medicaid in which the state as a government</p> <p>10 entity is paying directly for members or</p> <p>11 enrollee's benefits.</p> <p>12 Q. Okay.</p> <p>13 If I'm -- if I'm remembering</p> <p>14 the one article I've ever read about</p> <p>15 Medicaid correctly, the one that is directly</p> <p>16 paid by the state is known as -- I believe</p> <p>17 it's Medicaid fee-for-service.</p> <p>18 Is that right?</p> <p>19 A. Yes. That's correct.</p> <p>20 Q. Okay. Okay. I'm no Medicaid</p> <p>21 expert.</p> <p>22 Then Medicaid managed care, if</p> <p>23 I understand correctly, that is covered by a</p> <p>24 private organization that then either prior</p> <p>25 to or post delivery of the care receives a</p>	<p style="text-align: right;">Page 236</p> <p>1 L. Craft</p> <p>2 managed care organizations in Exhibit 8?</p> <p>3 A. Yes, you're exactly right.</p> <p>4 Although it's very easy, given the</p> <p>5 categorization of these plans to, for</p> <p>6 example, say I'm going to remove all</p> <p>7 Medicaid or I'm going to include different</p> <p>8 sub categories of Medicaid that are</p> <p>9 established in the IQVIA data.</p> <p>10 So this was an illustration for</p> <p>11 numerosity purposes that left in managed</p> <p>12 Medicaid, but they can just as easily be</p> <p>13 removed if that's ultimately what counsel</p> <p>14 determines is appropriate.</p> <p>15 Q. Let me back up because I --</p> <p>16 maybe I misheard you.</p> <p>17 Did you say you left in -- you</p> <p>18 left in managed Medicaid. Okay. But you</p> <p>19 cut Medicare -- Medicaid fee-for-service?</p> <p>20 A. Correct.</p> <p>21 Q. Okay.</p> <p>22 I understand from your prior</p> <p>23 testimony that the only other expert</p> <p>24 materials you've reviewed is the expert</p> <p>25 report of Tim Kosty; is that true?</p>
<p style="text-align: right;">Page 235</p> <p>1 L. Craft</p> <p>2 fee? I think it's known as a capitation; is</p> <p>3 that also correct?</p> <p>4 A. That's right. A capitation is</p> <p>5 simply a fixed fee for each individual who</p> <p>6 is receiving coverage. So it's like a</p> <p>7 premium.</p> <p>8 Q. Okay.</p> <p>9 In both cases, whether or not</p> <p>10 the state is directly paying the provider or</p> <p>11 the state is paying a managed care</p> <p>12 organization that then pays the provider,</p> <p>13 the state is paying some sum of money for</p> <p>14 Medicare care, right?</p> <p>15 A. Yes, but it is not providing</p> <p>16 benefits directly to consumers in the fee --</p> <p>17 in the managed care model. Instead, the</p> <p>18 price risk of products and services that are</p> <p>19 covered is shifted to the insurance company</p> <p>20 that provides that managed care coverage.</p> <p>21 Q. If I assume then -- but please,</p> <p>22 correct me if I'm wrong -- that what you</p> <p>23 just said, is that the basis for your</p> <p>24 exclusion of fee for service plans from the</p> <p>25 list shown in Exhibit 8 but the inclusion of</p>	<p style="text-align: right;">Page 237</p> <p>1 L. Craft</p> <p>2 A. That's correct.</p> <p>3 Q. Okay.</p> <p>4 If it is the case that one of</p> <p>5 the plaintiffs' other experts on damages</p> <p>6 excluded both Medicaid fee-for-service and</p> <p>7 Medicare managed care payors from a damages</p> <p>8 analysis, wouldn't that be inconsistent with</p> <p>9 your inclusion of Medicaid managed care</p> <p>10 organizations in your numerosity analysis?</p> <p>11 MR. STANOCH: Objection to</p> <p>12 form.</p> <p>13 Incomplete hypothetical.</p> <p>14 Misstates opinions.</p> <p>15 Vague.</p> <p>16 Go ahead.</p> <p>17 A. Well, it couldn't be</p> <p>18 inconsistent in the sense that I was here</p> <p>19 only attempting to establish numerosity and</p> <p>20 I do not know what -- precisely what the</p> <p>21 scope of Medicaid claims would be in the</p> <p>22 approved class definition.</p> <p>23 Clearly, you would want the</p> <p>24 ascertainability definition and scope to</p> <p>25 correspond with the damage scope. That's</p>

<p style="text-align: right;">Page 238</p> <p>1 L. Craft</p> <p>2 readily done using the available data. So</p> <p>3 it's -- a decision would have to be made.</p> <p>4 I, on my own initiative, left</p> <p>5 in managed care because that's typically</p> <p>6 what I do, but that doesn't mean that that</p> <p>7 needs to be the case ultimately and that's a</p> <p>8 decision that would have to be made, but</p> <p>9 it's one that can be implemented whichever</p> <p>10 direction you go using the available data.</p> <p>11 Q. As you prepared your opinion in</p> <p>12 this list of TPPs that we have here in</p> <p>13 Exhibit 8, did you count Medicare Part D</p> <p>14 plans as federally funded?</p> <p>15 A. I didn't count anything about</p> <p>16 funding sources. What I counted was whether</p> <p>17 they were government entities that were</p> <p>18 undertaking the obligation to provide</p> <p>19 benefits and as a result, I included in the</p> <p>20 class Medicare Part D plans because those</p> <p>21 are not government plans. Those are</p> <p>22 commercial plans, they are understood to be</p> <p>23 commercial plans throughout the industry.</p> <p>24 They are sponsored by commercial insurance</p> <p>25 companies, registered to provide insurance</p>	<p style="text-align: right;">Page 240</p> <p>1 L. Craft</p> <p>2 A. Yeah, that's generally correct.</p> <p>3 The data sources I'm proposing to use here</p> <p>4 do not include the CMS payments to Medicare</p> <p>5 prescription drug plans.</p> <p>6 Q. I think we could take Exhibit 8</p> <p>7 down for the time being. Let's go back to</p> <p>8 Exhibit 4, page 89, paragraph 60.</p> <p>9 I want to ask you about this</p> <p>10 Milliman, M-I-L-L-I-M-A-N, data that you</p> <p>11 discuss in terms of identifying state plans</p> <p>12 to exclude from the TPP class.</p> <p>13 I guess right off the bat, you</p> <p>14 haven't actually provided any Milliman Atlas</p> <p>15 data as part of your report, right?</p> <p>16 MR. STANOCH: Objection to</p> <p>17 form.</p> <p>18 A. No, I have not. That data</p> <p>19 would have to be purchased.</p> <p>20 Q. Okay. Then I guess that</p> <p>21 answers my next question.</p> <p>22 You haven't actually gone and</p> <p>23 obtained Milliman data for this case; is</p> <p>24 that right?</p> <p>25 A. That's correct.</p>
<p style="text-align: right;">Page 239</p> <p>1 L. Craft</p> <p>2 benefits and the fact that there are</p> <p>3 subsidies and reimbursements at various</p> <p>4 levels that are ultimately after the fact</p> <p>5 supplied to those plans typically in the --</p> <p>6 to the largest extent based on their total</p> <p>7 population in the plan, although there are</p> <p>8 also payments in connection with the</p> <p>9 individual drug purchases.</p> <p>10 Those subsequent reimbursements</p> <p>11 or contributions subsidies are, in my</p> <p>12 opinion, irrelevant to the question what did</p> <p>13 the payor who was obligated to provide the</p> <p>14 benefit actually pay.</p> <p>15 Q. The various data then that</p> <p>16 you've proposed using to identify the</p> <p>17 class -- the economic class losses in this</p> <p>18 case, would not reflect whatever subsidies</p> <p>19 or other payments from the government that</p> <p>20 Part D plans received?</p> <p>21 MR. STANOCH: Objection to</p> <p>22 form.</p> <p>23 Q. Is that fair to say?</p> <p>24 MR. STANOCH: Objection to</p> <p>25 form.</p>	<p style="text-align: right;">Page 241</p> <p>1 L. Craft</p> <p>2 Q. Have you ever obtained it for</p> <p>3 any reason in the past?</p> <p>4 MR. STANOCH: Objection.</p> <p>5 Just, again, cautioning the</p> <p>6 witness within the scope of other</p> <p>7 confidentiality orders, consulting</p> <p>8 arrangements, privilege, but go ahead.</p> <p>9 A. Not in connection with any</p> <p>10 matter where I've been a designated expert.</p> <p>11 Q. Now, in this paragraph, it</p> <p>12 says -- let me make sure we're on the right</p> <p>13 page. Let's do 39 onto 40.</p> <p>14 Here, it says that the data is</p> <p>15 considered authoritative and Milliman is</p> <p>16 recognized as the preeminent national expert</p> <p>17 in actuarial benefits analysis.</p> <p>18 This case does not involve</p> <p>19 actuarial benefits analysis, right?</p> <p>20 MR. STANOCH: Objection.</p> <p>21 Go ahead.</p> <p>22 A. I think what this is saying,</p> <p>23 actuarial is just being used as an adjective</p> <p>24 to modify benefits and what that means is</p> <p>25 the value of benefits over time and the</p>

<p style="text-align: right;">Page 242</p> <p>1 L. Craft</p> <p>2 amounts that are paid out in benefits</p> <p>3 compared to the cost of those benefits.</p> <p>4 Certainly we are looking at the product of</p> <p>5 benefits being paid out over time every time</p> <p>6 we see an insured claim that involves one of</p> <p>7 the at-issue VCDs.</p> <p>8 Q. So let me ask you then how --</p> <p>9 let's say you obtain Milliman data for this</p> <p>10 case.</p> <p>11 What do you do with it?</p> <p>12 MR. STANOCH: Objection to</p> <p>13 form.</p> <p>14 Incomplete hypothetical.</p> <p>15 A. So we come back to the question</p> <p>16 of self-funding versus fully insured. To</p> <p>17 the extent that a state government plan is</p> <p>18 fully insured, we don't have to do anything.</p> <p>19 It's in the class. What we're trying to do</p> <p>20 here is to say okay, if there's a</p> <p>21 self-funded government plan -- and by</p> <p>22 government, I should make very clear that</p> <p>23 what I mean is the state government entity.</p> <p>24 I specifically do not mean towns, cities and</p> <p>25 counties because they are not excluded in</p>	<p style="text-align: right;">Page 244</p> <p>1 L. Craft</p> <p>2 for a particular state agency or is it a</p> <p>3 commercial insurer. The reason for that</p> <p>4 cautious language there is because the</p> <p>5 funding status data doesn't go all the way</p> <p>6 back to 2010. The descriptions of all the</p> <p>7 plans that existed at the state level goes</p> <p>8 back to 2010, but funding is only available</p> <p>9 for the most recent probably two or three</p> <p>10 years now.</p> <p>11 Q. Certainly funding status can</p> <p>12 change over time, right?</p> <p>13 A. Well, that's a theoretical</p> <p>14 possibility, but it's not common.</p> <p>15 Government entities have a tendency --</p> <p>16 insofar as government entities are</p> <p>17 concerned.</p> <p>18 Now, these are benefits that</p> <p>19 are funded frequently through legislative</p> <p>20 appropriations. They are part of</p> <p>21 slow-moving government programs that don't</p> <p>22 just go to bid every year and say hey, I</p> <p>23 think we'll take on this risk this year, we</p> <p>24 had an insurer for it last year and then</p> <p>25 they flipped back the next year.</p>
<p style="text-align: right;">Page 243</p> <p>1 L. Craft</p> <p>2 the class definition. So they're still in</p> <p>3 there.</p> <p>4 But if we have a -- if we</p> <p>5 identify those plans, those health plans,</p> <p>6 that are self-funded by the state government</p> <p>7 entities such that the state government is,</p> <p>8 in fact, the payor of benefits, then we</p> <p>9 would exclude those from the class. I</p> <p>10 identify them in PBM data the same way we</p> <p>11 would for other plans: Take the plan</p> <p>12 number, the plan ID, the plan name, the plan</p> <p>13 year and pull those claims out of the claims</p> <p>14 data.</p> <p>15 Q. So I see in paragraph 60 you</p> <p>16 indicated that the Milliman data provides an</p> <p>17 indication of which agency or employee plans</p> <p>18 are at least currently self-funded.</p> <p>19 My question to you is what</p> <p>20 actually -- like what does it say in the</p> <p>21 Milliman data? What does the text read?</p> <p>22 MR. STANOCH: Objection to</p> <p>23 form.</p> <p>24 A. It specifically identifies who</p> <p>25 is paying for the benefits. Is it -- is it</p>	<p style="text-align: right;">Page 245</p> <p>1 L. Craft</p> <p>2 These tend to be pretty stable</p> <p>3 funding relationships over time just because</p> <p>4 you're talking about the bureaucracy and</p> <p>5 process that goes into creating government</p> <p>6 health plans.</p> <p>7 Q. Have you tracked the funding</p> <p>8 status of government health -- state</p> <p>9 government health plans over the last --</p> <p>10 gosh, I don't know -- ten years to get an</p> <p>11 estimate of how often these plans actually</p> <p>12 do change their funding status?</p> <p>13 A. No, I haven't done that</p> <p>14 analysis, except for in the Medicaid sector</p> <p>15 where the shift towards managed Medicaid has</p> <p>16 been large and rapid and we do have that</p> <p>17 identified on an annual basis, but I have</p> <p>18 not looked at government -- state employee</p> <p>19 plans to see how frequently their funding</p> <p>20 status has changed.</p> <p>21 Q. Let's go ahead and go to</p> <p>22 paragraph 51 on page 40.</p> <p>23 This is refers to the IQVIA</p> <p>24 Xponent data that you used for excluding</p> <p>25 some governmental plans from your list of</p>

Page 246

1 L. Craft
2 TPPs, right?
3 A. That's right.
4 Q. Now, within -- you're
5 describing a model type in this paragraph
6 and I guess I want to be clear for laypeople
7 like myself, laypersons like myself that
8 what a model type is.

9 So a model type is one of the
10 data fields in IQVIA Xponent data.

11 Right?

12 A. That's correct.

13 Q. Okay.

14 So you can sort by model type,
15 for example? Like you can add it to a
16 column and then sort, you know, I want
17 everything that's model type PBM, for
18 example, right?

19 A. That's right.

20 Q. Okay.

[illegible][illegible][illegible]

18 So there are -- that issue has
19 not been executed in the particular exhibit
20 you're looking at. I did not attempt to
21 parse the state employee plans. I merely
22 explained in my report that you could do so.

23 Q. Okay. I appreciate then the
24 clarification.

25 Let me ask it this way: You

Page 252

1 L. Craft
2 use this and only this data source.
3 What I said is you've got a
4 huge leg up here because we've already got
5 about 3,000 payors identified associated
6 with about 11,600 plans that are identified
7 TPPs. So you have to keep the purpose in
8 mind behind the exercise I was doing.
9 Q. Let me ask you about the head
10 start that you're saying we have here.
11 Assuming that it is, in fact,
12 around 3,000 TPPs involved with some number
13 that would need to be excluded, how do you
14 intend to match that -- those IQVIA data
15 with PBM information that you obtain in an
16 attempt to also identify TPPs?
17 MR. STANOCH: Objection to
18 form.
19 A. I'm not sure one needs to match
20 it. I'm just saying -- I can identify that
21 number of payors here, so we should have no
22 concerns about maybe having too small a
23 class that doesn't need the infrastructure
24 and the support of a class action format.
25 So I would use -- you recall that this

Page 253

1 L. Craft
2 morning as I was describing the data sources
3 that I would use to identify class members I
4 didn't say the IQVIA Xponent data. I said I
5 had used that for the purpose of showing
6 numerosity.
7 It is a stellar example of the
8 availability of information in the
9 pharmaceutical industry derived from the
10 very sources that I'm using that allows
11 classification by various attributes of
12 plans and that's what you're describing
13 correctly as model types. So there are
14 many, many model types as represented in the
15 managed care workbook -- effectively, the
16 glossary that we gave you -- and you can see
17 how those model types are subsets of
18 particular methods of payment.

<p style="text-align: right;">Page 254</p> <p>[REDACTED]</p> <p>16 Q. So is it your proposal in your 17 methodology for identifying TPP class 18 members, is it your proposal that you would 19 use IQVIA Xponent data? 20 MR. STANOCH: Objection to 21 form. 22 Asked and answered. 23 A. I have not proposed that I 24 would need to do that. I think it's a good 25 idea to make sure that the damage</p>	<p style="text-align: right;">Page 256</p> <p>1 L. Craft 2 check, a reconciliation. 3 Q. What would the initial source 4 be for the exclusion of state governmental 5 plan? 6 MR. STANOCH: Objection to 7 form. 8 Go ahead. 9 A. Right. So as I explained in my 10 report, first stop would be to request that 11 the PBMs together with their claims data 12 flag the state and federal government plans, 13 although by which I mean federal and 14 government plans where the federal or state 15 government is the payor, is the obligor. 16 And ideally, you would like them to do that. 17 Then I explain in my report at 18 some length that PBMs have the capability to 19 do that because they have specific lines of 20 business that are government entity plans. 21 They market specifically -- because those 22 plans are subject to separate regulations 23 and separate rules, they are treated as a 24 distinct line of business so that the states 25 can be sure there are no anti-kickback</p>
<p style="text-align: right;">Page 255</p> <p>1 L. Craft 2 calculation, which does use and rely upon 3 the IQVIA data, represents the same contours 4 of class definition as what I am proposing 5 to identify from the PBM data and 6 potentially retailer data, but I did not say 7 that I would use the Xponent data to 8 identify class members. 9 I can tell you right now you've 10 got several thousand of them, but that's not 11 a final step. I was doing this as an 12 illustration of the size of the class. 13 Q. Would you use IQVIA Xponent 14 data to exclude class members? 15 MR. STANOCH: Objection to 16 form. 17 A. If I saw that a particular 18 group of plans were, for example, identified 19 as directly funded by the state -- so a 20 state assistance program is an example -- a 21 state assistance program, yeah, I might 22 cross check against this list to make sure 23 that in the PBM data I was catching that 24 state assistance program to eliminate it. 25 This would just effectively be a double</p>	<p style="text-align: right;">Page 257</p> <p>1 L. Craft 2 violations in the way the plans are being 3 operated and that other regulations are 4 being complied with. 5 So the first step would be to 6 ask the PBMs to flag where the plan is a 7 government -- a federal or state government 8 entity. I have no problem with the federal. 9 It's not really necessary to ask them to do 10 that because we can see them by name. So we 11 can see VA, IHS, CHIP in the PBM plan data 12 where the client name and account are 13 described. 14 With regard to the state plans, 15 we would ask that the PBMs identify them. 16 But let's just say for some reason that data 17 is not complete or not supplied. That flag 18 is not complete or not supplied. Then the 19 various other sources that I identify in my 20 report, including things like the Milliman 21 Atlas or even potentially a cross check 22 against this IQVIA data, state legislature 23 list or if necessary, an inquiry to the 24 state personnel authority for each of the 25 states could be used to make that</p>

<p style="text-align: right;">Page 258</p> <p>1 L. Craft</p> <p>2 distinction if we had to go to those</p> <p>3 secondary sources of information.</p> <p>4 Q. Can we go to paragraph 62, page</p> <p>5 41 of Exhibit 4, please? Actually, we don't</p> <p>6 need to change the exhibit, Ms. Craft. I</p> <p>7 forgot to ask you one question.</p> <p>8 We talked a minute ago about</p> <p>9 which exclusions you tried to apply to the</p> <p>10 list of TPPs in Exhibit 8.</p> <p>11 Did you try to</p> <p>12 exclude defendants and defendant affiliates</p> <p>13 from Exhibit 8?</p> <p>14 A. No, I did not because I was not</p> <p>15 supplied with a list of those entities that</p> <p>16 I could apply.</p> <p>17 Q. We could go back to that</p> <p>18 exhibit, Exhibit 4, page 41, paragraph 62.</p> <p>19 I want to focus on the last sentence here.</p> <p>20 "If any uncertainty remained, a</p> <p>21 look up online or a contact to the state's</p> <p>22 benefit office could confirm funding</p> <p>23 information."</p> <p>24 I guess my question is have you</p> <p>25 ever contacted a state's benefits office to</p>	<p style="text-align: right;">Page 260</p> <p>1 L. Craft</p> <p>2 consider making -- even if it was 50</p> <p>3 outreaches to 50 states, that's not a hugely</p> <p>4 burdensome or time consuming task.</p> <p>5 Q. All right. Let's go ahead and</p> <p>6 turn to paragraph 64 of your report. I know</p> <p>7 we talked about some of this information</p> <p>8 earlier in your testimony today, Ms. Craft,</p> <p>9 and so I'm going to do my level best to not</p> <p>10 retrod old ground. But bear with me if I</p> <p>11 need to ask some questions to understand</p> <p>12 what's going on here.</p> <p>13 Okay?</p> <p>14 A. Sure.</p> <p>15 Q. I appreciate that.</p> <p>16 Starting off in paragraph 64,</p> <p>17 your report stays that the NCPDP system is</p> <p>18 used to route data about the claim to the</p> <p>19 appropriate PBM for adjudication and that</p> <p>20 the transmitted data need to be sufficient</p> <p>21 for the PBM to identify the proper billing</p> <p>22 party, the one to whom it will charge the</p> <p>23 drug cost net of consumer cost sharing.</p> <p>24 As you use in this paragraph,</p> <p>25 proper billing party is not necessarily a</p>
<p style="text-align: right;">Page 259</p> <p>1 L. Craft</p> <p>2 inquire about the funding information of any</p> <p>3 of its employee insurance plans?</p> <p>4 A. Not by phone, but certainly</p> <p>5 we've done web look ups to their personnel</p> <p>6 sites. Absolutely.</p> <p>7 Q. Was that for the purpose of</p> <p>8 applying a class exclusion?</p> <p>9 MR. STANOCH: Objection.</p> <p>10 Just caution you with any</p> <p>11 protective order or consulting work</p> <p>12 privilege.</p> <p>13 THE WITNESS: Thank you for</p> <p>14 that reminder.</p> <p>15 A. I don't know whether it was</p> <p>16 specifically for the purpose of applying</p> <p>17 class exclusions. I just know that</p> <p>18 periodically we do have to investigate the</p> <p>19 existence of plans and their funding status</p> <p>20 from state entities and in some cases the</p> <p>21 historical records are pretty good online</p> <p>22 and in some cases they're incomplete and you</p> <p>23 might have to go to the personnel office to</p> <p>24 find out.</p> <p>25 By the way, I don't personally</p>	<p style="text-align: right;">Page 261</p> <p>1 L. Craft</p> <p>2 TPP, correct?</p> <p>3 A. It could be an ASO. I call it</p> <p>4 a proper billing party here.</p> <p>5 Q. Okay.</p> <p>6 Can we go back to page 16 of</p> <p>7 your report, figure three?</p> <p>8 Now here, this is where on page</p> <p>9 15 we've got this outline of various forms</p> <p>10 of NCPDP data that are exchanged in the</p> <p>11 course of a transaction at a pharmacy,</p> <p>12 right?</p> <p>13 A. Yes. These are some of the</p> <p>14 fields that are exchanged.</p> <p>15 Q. I'm going to go one at a time</p> <p>16 through these.</p> <p>17 Cardholder ID, that is going to</p> <p>18 be an alpha numeric combination of</p> <p>19 characters, right?</p> <p>20 A. Yes.</p> <p>21 Q. Okay.</p> <p>22 That's intended to basically</p> <p>23 tell the PBM who was getting -- the patients</p> <p>24 associated with the prescription, right?</p> <p>25 A. That's right.</p>

<p style="text-align: right;">Page 262</p> <p>1 L. Craft</p> <p>2 Q. Okay.</p> <p>3 Does it convey any other</p> <p>4 information?</p> <p>5 A. No. It just uniquely</p> <p>6 identifies the individual for whom --</p> <p>7 Q. Okay.</p> <p>8 So what might -- sorry about</p> <p>9 that. Go ahead and finish.</p> <p>10 A. Uniquely identifies the</p> <p>11 individual for whom the prescription is</p> <p>12 written.</p> <p>13 Q. Plan ID is the next one.</p> <p>14 That's in column two. Plan ID is also a</p> <p>15 alpha numeric combination of characters,</p> <p>16 right?</p> <p>17 A. That's right.</p> <p>18 Q. Is that something I would see</p> <p>19 on my insurance card?</p> <p>20 A. It sure is.</p> <p>21 Q. Other than -- well, let me ask</p> <p>22 you this: Who assigns a plan ID?</p> <p>23 A. So the plan ID is assigned by</p> <p>24 the plan itself and attaches to that plan.</p> <p>25 Regardless of what claims are being</p>	<p style="text-align: right;">Page 264</p> <p>1 L. Craft</p> <p>2 what we were talking about this morning.</p> <p>3 Q. Okay. I really just want to</p> <p>4 focus on what goes -- right now, what goes</p> <p>5 from pharmacy to PBM. Okay?</p> <p>6 A. Okay.</p> <p>7 Q. That's what's represented here</p> <p>8 in this NCPDP data --</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Great. All right.</p> <p>11 The same with --</p> <p>12 A. Sorry. I'm sorry to interrupt</p> <p>13 you, but I need to correct what I just said.</p> <p>14 So obviously, the information</p> <p>15 in the last box, that price allocation,</p> <p>16 that's coming from the PBM back. That is</p> <p>17 not generated by the pharmacy. The pharmacy</p> <p>18 will put in a submitted cost for the</p> <p>19 product, but that's just the "We think you</p> <p>20 should pay us X."</p> <p>21 What actually controls is this</p> <p>22 total price field and the make up of price</p> <p>23 in the return message from the PBM.</p> <p>24 Does that make sense?</p> <p>25 Understand?</p>
<p style="text-align: right;">Page 263</p> <p>1 L. Craft</p> <p>2 processed, everything will be tied back to</p> <p>3 that plan ID.</p> <p>4 Q. What do you mean, everything</p> <p>5 will be tied back?</p> <p>6 A. All claims activity is -- will</p> <p>7 be associated with -- for that plan will be</p> <p>8 associated with that plan ID.</p> <p>9 Q. Now, a plan ID doesn't actually</p> <p>10 list who the plan is, right?</p> <p>11 A. The plan ID does not list the</p> <p>12 name in words that you and I could read. I</p> <p>13 mean, it may, but it may not include the</p> <p>14 actual words associated. So it may not say</p> <p>15 Blue Shield PPO, although you'll see that on</p> <p>16 your card.</p> <p>17 I think Mr. Kosty says why type</p> <p>18 that in, the pharmacist may not type in Blue</p> <p>19 Shield PPO. The reason they don't have to</p> <p>20 type it in is because they've got the plan</p> <p>21 ID and the plan ID specifically tells the</p> <p>22 PBM which plan we're talking about and the</p> <p>23 PBM records have the name of that plan, the</p> <p>24 full name of that plan. They have the</p> <p>25 linked information for that plan ID. That's</p>	<p style="text-align: right;">Page 265</p> <p>1 L. Craft</p> <p>2 Q. I think it does make sense.</p> <p>3 So the first four boxes in</p> <p>4 figure three are pharmacy to PBM, the</p> <p>5 last -- the fifth box is PBM back to</p> <p>6 pharmacy?</p> <p>7 A. Correct.</p> <p>8 Q. Great. Easy enough.</p> <p>9 So I don't know if I'm going</p> <p>10 out of order here, I think I might. BIN or</p> <p>11 BIN number, that's also known as IIN now,</p> <p>12 right?</p> <p>13 A. That's correct.</p> <p>14 Q. Okay.</p> <p>15 The BIN is only going to</p> <p>16 identify to which entity a claim needs to be</p> <p>17 sent for processing and payment. Well, is</p> <p>18 that your understanding?</p> <p>19 A. I think that is exactly</p> <p>20 Mr. Kosty's language. It is a larger</p> <p>21 category than plan ID. It does identify</p> <p>22 which PBM to send this claim to. That's</p> <p>23 correct. It identifies which PBM to send it</p> <p>24 to. So you may have multiple plan IDs that</p> <p>25 are routed using the same BIN number. So</p>

<p style="text-align: right;">Page 266</p> <p>1 L. Craft</p> <p>2 they're getting to the same PBM, using the</p> <p>3 same BIN number, but with different plan IDs</p> <p>4 and group IDs associated with the claims.</p> <p>5 Q. Okay.</p> <p>6 The BIN, again, is just going</p> <p>7 to be some alpha numeric combination of</p> <p>8 letters and numbers, yes?</p> <p>9 A. That's right.</p> <p>10 Q. Okay.</p> <p>11 It's not going to reflect the</p> <p>12 funding status of the plan?</p> <p>13 A. Standalone, it will not.</p> <p>14 Q. Nor will it even -- that's</p> <p>15 right. It's not even going to list the name</p> <p>16 of the plan, correct?</p> <p>17 MR. STANOCH: Objection.</p> <p>18 A. Correct.</p> <p>19 Q. Okay.</p> <p>20 The plan ID -- I'm going to go</p> <p>21 back. I missed a question.</p> <p>22 The plan ID itself does not</p> <p>23 indicate whether there's an ASO or TPA</p> <p>24 relationship, does it?</p> <p>25 A. If you were just reading those</p>	<p style="text-align: right;">Page 268</p> <p>1 L. Craft</p> <p>2 A. Yes. It's routinely used to</p> <p>3 identify benefit packages. So to</p> <p>4 differentiate one group of claimants from</p> <p>5 another based on the particular benefit</p> <p>6 package that's going to be applied in</p> <p>7 deciding who pays what.</p> <p>8 Q. I think that PCN is actually</p> <p>9 just -- it's a possible field. It's not a</p> <p>10 required field to be transmitted along from</p> <p>11 the pharmacy, right?</p> <p>12 A. Right. And that's because if</p> <p>13 we have a plan that only has one benefit</p> <p>14 package, you don't really need a PCN because</p> <p>15 there's only one benefit package it can</p> <p>16 attach to. So the processor control number</p> <p>17 is a discretionary number used by the PBM to</p> <p>18 expedite its own claims processing by</p> <p>19 marking which benefit structure the</p> <p>20 particular claims should be applied to.</p> <p>21 Q. And again, that's just going to</p> <p>22 be another code or number, right?</p> <p>23 A. That's right.</p> <p>24 Q. It's not going to reflect</p> <p>25 funding status of the plan?</p>
<p style="text-align: right;">Page 267</p> <p>1 L. Craft</p> <p>2 code numbers, you wouldn't be able to say</p> <p>3 whether that's an ASO or a TPA, but when</p> <p>4 that plan ID is then used in combination of</p> <p>5 these other items of information by the PBM,</p> <p>6 that's when you break it into a specific</p> <p>7 account that may be denominated as ASO or</p> <p>8 TPA.</p> <p>9 Q. Okay. So on its own -- sorry,</p> <p>10 I didn't mean to interrupt you. Were you</p> <p>11 finished?</p> <p>12 A. Yes. Go ahead.</p> <p>13 Q. Okay.</p> <p>14 On its own, the plan ID is not</p> <p>15 going to indicate TPA or ASO or fully</p> <p>16 insured or self-insured? None of those</p> <p>17 things, right?</p> <p>18 A. You could not read that number</p> <p>19 and glean that information from just the</p> <p>20 plan ID number.</p> <p>21 Q. Let's move on to processor</p> <p>22 control number or PCN.</p> <p>23 PCN can identify a plan, it can</p> <p>24 also identify something like a benefits</p> <p>25 package, right?</p>	<p style="text-align: right;">Page 269</p> <p>1 L. Craft</p> <p>2 A. Standing independently, that</p> <p>3 code number will not. It would simply</p> <p>4 repeat my prior answer, that these</p> <p>5 combinations of numbers allow the PBM to</p> <p>6 segregate this claims processing data and</p> <p>7 may link directly to an ASO or TPA account</p> <p>8 or to a fully insured account.</p> <p>9 Q. Then would you say the same for</p> <p>10 the last one, the group ID?</p> <p>11 MR. STANOCH: Objection to</p> <p>12 form.</p> <p>13 A. I mean, yes, that's one of the</p> <p>14 elements of information that the PBM gets</p> <p>15 that locks it in with the correct payor, the</p> <p>16 correct plan, the correct responsible party</p> <p>17 and whatever information is in that plan set</p> <p>18 up to be able to adjudicate the claim, as</p> <p>19 well as all of the historical information</p> <p>20 about the individual consumer represented by</p> <p>21 that card holder ID.</p> <p>22 Q. Now, in your last answer -- and</p> <p>23 I want to make sure that we're clear.</p> <p>24 In your last answer that you</p> <p>25 just gave, you said it's going to indicate</p>

<p style="text-align: right;">Page 270</p> <p>1 L. Craft</p> <p>2 the correct payor. Again, that payor is</p> <p>3 just the -- the PBM's client is the payor</p> <p>4 you're referring to in that answer, correct?</p> <p>5 A. Yes. I'll go back to the</p> <p>6 language in the report. The proper billing</p> <p>7 party.</p> <p>8 Q. Okay.</p> <p>9 Is proper billing party and</p> <p>10 client in terms of the PBM's client, are</p> <p>11 those synonymous?</p> <p>12 MR. STANOCH: Objection to</p> <p>13 form.</p> <p>14 A. Not quite. Because there may</p> <p>15 be differences in who you bill for different</p> <p>16 accounts or groups within a client. So a</p> <p>17 given client could have many plans and those</p> <p>18 might have, for example, different billing</p> <p>19 responsibilities and coordinates. So we</p> <p>20 need these numbers to work in combination to</p> <p>21 be able to identify as the PBMs</p> <p>22 automatically and instantaneously do the</p> <p>23 proper billing for any individual claim.</p> <p>24 Q. Can we go to paragraph 65 of</p> <p>25 your report, please, to be on page, I think,</p>	<p style="text-align: right;">Page 272</p> <p>1 L. Craft</p> <p>2 message to the PBM and then PBM is obviously</p> <p>3 going to return a response.</p> <p>4 What paragraph 65 is talking</p> <p>5 about is what happens in the split second</p> <p>6 when that pharmacy message reaches the PBM.</p> <p>7 Q. Right. Okay. And that's, I</p> <p>8 guess, what I want to differentiate between.</p> <p>9 So there's the pharmacy message, which is</p> <p>10 what I'm calling the NCPDP data for purposes</p> <p>11 of the next however many questions, and then</p> <p>12 I guess I would just refer to the additional</p> <p>13 data PBMs maintain about their clients. I</p> <p>14 would call that the set up data. But is</p> <p>15 there an appropriate -- okay. You're</p> <p>16 shaking your head no.</p> <p>17 So why is that not accurate?</p> <p>18 A. Because client name and account</p> <p>19 name and group name and those unique ID</p> <p>20 numbers associated with those are all</p> <p>21 portions of the claims data. They're right</p> <p>22 there, reported, printed out as part of the</p> <p>23 claims data. So to say that that is plan</p> <p>24 set up data is wrong.</p> <p>25 Those elements are pulled as</p>
<p style="text-align: right;">Page 271</p> <p>1 L. Craft</p> <p>2 43. I know we've danced around it a little</p> <p>3 bit today about some of the additional data</p> <p>4 PBMs maintain about their clients, as you</p> <p>5 refer to in paragraph 65 in the first</p> <p>6 sentence.</p> <p>7 First off, I guess I kind of</p> <p>8 want to differentiate. This is more</p> <p>9 housekeeping than anything.</p> <p>10 The information we were talking</p> <p>11 about in figure three just a moment ago, I</p> <p>12 like to call that NCPDP data. Is that -- to</p> <p>13 refer to those elements -- the plan ID, the</p> <p>14 group, the PCN and the BIN -- if I refer to</p> <p>15 those as NCPDP data, is that agreeable to</p> <p>16 you?</p> <p>17 A. Well, it's not accurate,</p> <p>18 because NCPDP is the messaging standard that</p> <p>19 governs the direction of -- the flow of</p> <p>20 information in both directions. So I'm</p> <p>21 happy if you want to describe that as the</p> <p>22 pharmacy message to the PBM. That's what</p> <p>23 we've been -- those first four out of five</p> <p>24 boxes on the figure that we were just</p> <p>25 looking at are elements of that pharmacy</p>	<p style="text-align: right;">Page 273</p> <p>1 L. Craft</p> <p>2 part of the claim adjudication process. You</p> <p>3 need not leave the claim adjudication</p> <p>4 database or engine in order to obtain those</p> <p>5 values. They happen immediately.</p> <p>6 So let's not get confused and</p> <p>7 think that we have got to go to some other</p> <p>8 database to link up to all of this</p> <p>9 identifying information. It happens</p> <p>10 immediately in the claims engine.</p> <p>11 What we were talking about</p> <p>12 before with the plan set up sheets is</p> <p>13 details. So things like billing</p> <p>14 coordinates, you know, full legal names,</p> <p>15 contacts, then the information about ASO,</p> <p>16 TPA, what's the funding status, that</p> <p>17 information we're talking about in the</p> <p>18 separate plan worksheets, but the</p> <p>19 information you see described to you in 65</p> <p>20 here is all part of the claims adjudication</p> <p>21 database.</p> <p>22 Q. Okay.</p> <p>23 So instead of referring to</p> <p>24 those as set up data, I'll refer to them</p> <p>25 instead as just the additional data in the</p>

<p style="text-align: right;">Page 274</p> <p>1 L. Craft</p> <p>2 collective.</p> <p>3 Okay?</p> <p>4 A. Okay.</p> <p>5 Q. All right. Great.</p> <p>6 Is it your contention that all</p> <p>7 PBMs follow this client account and group</p> <p>8 hierarchy?</p> <p>9 A. Yes. Yes. I mean, there may</p> <p>10 be clients where you don't have sub</p> <p>11 accounts, so that doesn't mean that the</p> <p>12 field is invariably used. It does mean that</p> <p>13 this kind of hierarchical structure is</p> <p>14 routinely used. There are --</p> <p>15 Q. Do all -- sorry.</p> <p>16 A. There are cases where I've seen</p> <p>17 claims reported with collapsed values of</p> <p>18 claim and client and account together and</p> <p>19 grouped separate. But generally, this is</p> <p>20 the standard hierarchical structure used by</p> <p>21 all of major PBMs.</p> <p>22 Q. So then if I'm understanding</p> <p>23 you correctly, it's your contention that --</p> <p>24 well, let me ask you this: Do all PBMs</p> <p>25 require the use of the group description?</p>	<p style="text-align: right;">Page 276</p> <p>1 L. Craft</p> <p>2 payor name. Some call it customer name.</p> <p>3 They're immaterially different. It's just</p> <p>4 how those fields are labeled in the data.</p> <p>5 Sometimes group description may</p> <p>6 be called employer group by some PBMs. It</p> <p>7 is called employer group by some PBMs.</p> <p>8 It's not at all difficult to</p> <p>9 recognize which of these represent -- these</p> <p>10 fields represent the same thing when</p> <p>11 traveling from one PBM to another. But</p> <p>12 there are minor differences in naming</p> <p>13 conventions that can both be observed in the</p> <p>14 data and that are explained in the data</p> <p>15 dictionaries that all PBMs keep.</p> <p>16 Q. For purposes of identifying</p> <p>17 class members, have you actually taken this</p> <p>18 additional data from multiple PBMs and</p> <p>19 actually combined it together to produce a</p> <p>20 list of class members?</p> <p>21 MR. STANOCH: Objection to</p> <p>22 form.</p> <p>23 Asked and answered.</p> <p>24 Go ahead.</p> <p>25 A. I've certainly combined PBM</p>
<p style="text-align: right;">Page 275</p> <p>1 L. Craft</p> <p>2 MR. STANOCH: Objection to</p> <p>3 form.</p> <p>4 A. I'm trying to think if I've</p> <p>5 ever seen an entry without a group. When</p> <p>6 you say require it, if there's a single</p> <p>7 group ensured under a plan ID that has only</p> <p>8 a single benefit package, it wouldn't be an</p> <p>9 essential number. But that doesn't mean</p> <p>10 that as an overall data structure in</p> <p>11 hierarchy these don't exist, these fields</p> <p>12 don't exist. It just means you don't need</p> <p>13 them in a particular case.</p> <p>14 Q. Sure. Okay. I guess let me</p> <p>15 make sure I understand.</p> <p>16 You would say all PBMs do at</p> <p>17 least have a group field within this</p> <p>18 additional data even if it's not used in a</p> <p>19 particular client's case?</p> <p>20 MR. STANOCH: Objection to</p> <p>21 form.</p> <p>22 A. Yes. Yes, I would. I want to</p> <p>23 make clear to you that I'm using language</p> <p>24 from the most commonly used language, but</p> <p>25 for example, some PBMs call that client name</p>	<p style="text-align: right;">Page 277</p> <p>1 L. Craft</p> <p>2 data across multiple PBMs to demonstrate</p> <p>3 that that can be done. I have not had the</p> <p>4 opportunity to carry out that exercise on</p> <p>5 full productions, as I explained to you</p> <p>6 earlier in the day, in order to arrive at a</p> <p>7 list.</p> <p>8 But the step that we're talking</p> <p>9 about, the ability to merge data from</p> <p>10 multiple PBM sources, is, contrary to what</p> <p>11 Mr. Kosty says, not technologically or</p> <p>12 intellectually hard. It is -- these fields</p> <p>13 are both intuitive, there are common</p> <p>14 structures adopted by the PBMs because</p> <p>15 that's what allows them to deliver the</p> <p>16 functionality that all of these health plans</p> <p>17 need and there are data dictionaries that if</p> <p>18 you have any confusion can resolve that</p> <p>19 confusion.</p> <p>20 I have seen cases where the</p> <p>21 components of a payment may be differently</p> <p>22 labeled. So ingredient cost may not be</p> <p>23 called ingredient cost. It may be something</p> <p>24 else. But I've never found that I was</p> <p>25 unable to resolve those differences.</p>

Page 278

1 L. Craft
2 And this is, as I mentioned
3 earlier today, a standard part of data
4 processing whenever you are engaged in a
5 multiple data source analysis, whether in
6 pharmaceuticals or any place else in the
7 world, it's a standard process that
8 everybody uses. So there's nothing --
9 sorry, go ahead. I'm done.
10 Q. My fault.
11 The combination that you
12 referred to that you have done, I have two
13 quick questions about that.
14 Number one: Did that
15 combination include the additional data
16 referred to here in paragraph 65?
17 A. The additional data being the
18 claim -- the client name and ID, the account
19 name and ID and the group description and
20 ID? Is that what you're --
21 Q. That's right.
22 A. Yes. Yes.
23 Q. Are you able to -- and I'm
24 asking and I'm sure your counsel will tell
25 you not to if you can't -- but are you able

Page 279

1 L. Craft
2 to say a case where that happened, where
3 that's been done?
4 MR. STANOCH: Ms. Craft, I
5 caution you not to reveal any
6 information subject to a protective
7 order or a privilege of any kind.
8 A. I can't reveal specific cases,
9 but I'm going to have to simply explain that
10 this is pretty routine. When we intake
11 data, whether it's from a third-party payor,
12 which it might be, a big insurance company
13 or a pharmacy or a PBM, the literally very
14 first thing we do after we inventory the
15 data to determine its completeness, its
16 coverage over time periods and products, the
17 next thing we do is attempt to reconcile the
18 naming conventions such that we know we're
19 looking at the same value in entity A's
20 production as we see somewhere else in
21 entity B's production.
22 So standardization of field
23 names is routine. It's also a routine part
24 of evaluating the adequacy and completeness
25 of the data. We look at the field reports

Page 280

1 L. Craft
2 and say do we have everything we need here,
3 do I see the consumer share, do I see the
4 dispensing fee, do I see the TPP share, do I
5 see the fill date, etc., etc., etc., and
6 it's just -- I mean, it's a little bit like
7 you're going to take off in a plane and you
8 check each of the controls, check, check,
9 check, check, it's here, it's here, it's
10 here. If there's any confusion, you go to
11 the data dictionary or you go back and say
12 you're missing some fields, which happens.
13 Q. All right. Let's go to
14 paragraph 66 of your report --
15 MR. STANOCH: Mr. Dorner, is
16 everything good on your side.
17 MR. DORNER: Yes, just
18 conferring briefly.
19 Q. Looking at paragraph 66 of your
20 report, Ms. Craft, you say here that "The
21 TPP (ultimate payor of claims) typically
22 appears in the client/carrier field of the
23 PBM data, whether it is self funded or fully
24 insured plan."
25 My first question is

Page 281

1 L. Craft
2 client/carrier, is that the same thing that
3 you were referring to in the previous
4 paragraph as the client field?
5 A. Yes. Yes. This -- sometimes
6 it's reported as carrier because, of course,
7 most of the time, these are insurance
8 companies, and sometimes it's called client.
9 Those words are used interchangeably among
10 PBMs for that field.
11 Q. Okay.
12 Then when you -- just beyond
13 that, you used the term PBM data, which is,
14 I know, a term we covered or talked about
15 earlier.
16 I guess I'm wondering what are
17 you referring to as PBM data here?
18 Let me withdraw that question
19 and ask it a different way.
20 When you refer to PBM data
21 here, is that the same thing as the
22 additional data that we were talking about
23 in paragraph 65?
24 A. It's the claims data --
25 MR. STANOCH: Objection to

<p style="text-align: right;">Page 282</p> <p>1 L. Craft</p> <p>2 form.</p> <p>3 A. I'm talking about the claims</p> <p>4 data. The data that reports all of the</p> <p>5 claims that came to the PBM for adjudication</p> <p>6 and links each of them to their carrier</p> <p>7 account group, divides up the price,</p> <p>8 identifies the product. That claims data</p> <p>9 includes this information. The same</p> <p>10 information -- these same fields are present</p> <p>11 elsewhere, but my reference here, in talking</p> <p>12 about the PBM data, is PBM claims data.</p> <p>13 Q. Okay.</p> <p>14 And so -- if this is wrong, you</p> <p>15 can tell me I'm wrong.</p> <p>16 When I see PBM data here, I</p> <p>17 guess I'm hearing you to say that's the</p> <p>18 NCPDP pharmacy message plus the additional</p> <p>19 data -- talking about the client account and</p> <p>20 group -- equals the PBM claims data.</p> <p>21 Is that accurate?</p> <p>22 MR. STANOCH: Objection to</p> <p>23 form.</p> <p>24 Misstates testimony.</p> <p>25 Go ahead.</p>	<p style="text-align: right;">Page 284</p> <p>1 L. Craft</p> <p>2 we're trying to do here.</p> <p>3 Q. Now, in paragraph 66, you say,</p> <p>4 about the middle of the paragraph, "The TPP</p> <p>5 ultimate payor of claims typically appears</p> <p>6 in the client/carrier field of the TPP</p> <p>7 data."</p> <p>8 I'll just stop reading there</p> <p>9 because I think that's all that I need. I</p> <p>10 don't actually see any support for that</p> <p>11 contention in your report, so what is the</p> <p>12 basis for that contention?</p> <p>13 MR. STANOCH: Objection to</p> <p>14 form.</p> <p>15 A. The scope of the next sentence,</p> <p>16 which tells you when that's not true.</p> <p>17 You've got to read the two sentences</p> <p>18 together.</p> <p>19 Q. Okay.</p> <p>20 So is it your testimony that</p> <p>21 the TPP will always appear in the</p> <p>22 client/carrier field of PBM data unless that</p> <p>23 TPP has hired an ASO or a TPA?</p> <p>24 MR. STANOCH: Objection to</p> <p>25 form.</p>
<p style="text-align: right;">Page 283</p> <p>1 L. Craft</p> <p>2 A. The PBM claims data is</p> <p>3 typically a limited set of fields that are</p> <p>4 designed to run efficiently and to be suited</p> <p>5 for billing purposes and therefore there may</p> <p>6 be many pieces of information included in</p> <p>7 the pharmacy message or the PBM return that</p> <p>8 are not included in the claims data.</p> <p>9 We don't need to know those</p> <p>10 pieces of information for the purpose of</p> <p>11 this or the other cases I'm involved in</p> <p>12 typically. So -- but there are other</p> <p>13 fields. For example, dispenses written</p> <p>14 field, why was a particular brand dispensed</p> <p>15 rather than a generic? That kind of thing.</p> <p>16 There are messages -- the</p> <p>17 pharmacy asks for one dollar amount, but the</p> <p>18 PBM writes back in its return and says no,</p> <p>19 it's going to be the following dollar</p> <p>20 amount.</p> <p>21 There's a lot of additional</p> <p>22 information that is not necessarily</p> <p>23 preserved in the claims data. Sometimes it</p> <p>24 is produced with the claims data, sometimes</p> <p>25 it's not, but it's not important to what</p>	<p style="text-align: right;">Page 285</p> <p>1 L. Craft</p> <p>2 Asked and answered.</p> <p>3 Misstates the testimony.</p> <p>4 Misstates the report.</p> <p>5 Go ahead.</p> <p>6 A. But that is generally true,</p> <p>7 that if the -- unless there's an</p> <p>8 intermediary, unless there's a TPA or an ASO</p> <p>9 in the middle of that relationship between</p> <p>10 the PBM and the TPP, then it's going to be</p> <p>11 the TPP who will appear in the client</p> <p>12 carrier field because that's -- somebody's</p> <p>13 got to contract with the PBM for these</p> <p>14 services. Somebody is the PBM's client.</p> <p>15 They don't just do this willy nilly. They</p> <p>16 do it for specific clients for specific</p> <p>17 purposes.</p> <p>18 Your choice as to who that</p> <p>19 client is is either the TPP, i.e. the big</p> <p>20 old insurance company that is paying the</p> <p>21 claims, or a self-funding plan that's chosen</p> <p>22 to contract directly with the PBM or -- so</p> <p>23 those are the clients in that case, right?</p> <p>24 They're going to show up in the</p> <p>25 client/carrier field because they're the</p>

<p style="text-align: right;">Page 286</p> <p>1 L. Craft</p> <p>2 contracting entity that's going to get</p> <p>3 billed directly by the PBM for the payment.</p> <p>4 There is an exception to that</p> <p>5 general rule, which is described in the next</p> <p>6 sentence, which is if the third-party payor</p> <p>7 hires an intermediary, either an ASO or a</p> <p>8 third-party administrator, and assigns to</p> <p>9 that entity the responsibility to contract</p> <p>10 with the PBM for claims processing. In that</p> <p>11 case, you may have a situation where the</p> <p>12 client field is the name of that ASO or TPA</p> <p>13 rather than the underlying plan sponsor.</p> <p>14 Q. I just want to back up to --</p> <p>15 what I was getting at was you mentioned it's</p> <p>16 a general rule that the ultimate payor of</p> <p>17 claims -- assuming there's not an ASO or a</p> <p>18 TPA, it's a general rule, you said, that the</p> <p>19 TPP would appear in the client/carrier</p> <p>20 field.</p> <p>21 How often is that not the case?</p> <p>22 MR. STANOCH: Objection to</p> <p>23 form.</p> <p>24 Asked and answered.</p> <p>25 Misstates prior testimony.</p>	<p style="text-align: right;">Page 288</p> <p>1 L. Craft</p> <p>2 I'm not bearing this risk, I'm going to go</p> <p>3 buy insurance from an insurance company and</p> <p>4 the answer is about 88% of the time, that's</p> <p>5 what they do. About 88% of the employer and</p> <p>6 union plans are with regard to</p> <p>7 pharmaceuticals. The prescription drug</p> <p>8 benefits are fully insuring those benefits.</p> <p>9 So we start with the situation</p> <p>10 where it is not impossible, but it is pretty</p> <p>11 darned unusual where you are fully insuring</p> <p>12 those benefits for the insurer not to appear</p> <p>13 in the client or carrier field because</p> <p>14 insurers normally have their own preexisting</p> <p>15 relationships with PBMs. In fact, many of</p> <p>16 them are affiliated with or owned by or own</p> <p>17 those -- the related entities.</p> <p>18 So the tie between the insurer</p> <p>19 that would be acting as an ASO and a</p> <p>20 particular PBM is very strong. So we would</p> <p>21 typically expect that when we've got a fully</p> <p>22 insured employee or -- employee or union</p> <p>23 plan that it's going to be the insurer</p> <p>24 that's going to show up in the client</p> <p>25 carrier name.</p>
<p style="text-align: right;">Page 287</p> <p>1 L. Craft</p> <p>2 You may try to answer.</p> <p>3 A. Okay. I'm going to have to</p> <p>4 give you some numbers in order to do this.</p> <p>5 So the exception is limited to situations</p> <p>6 where a self-funding plan sponsor --</p> <p>7 typically, an employee or a union that has</p> <p>8 elected to pay for benefits -- directly</p> <p>9 hires an ASO or a TPA.</p> <p>10 So the first thing we want to</p> <p>11 know is -- because this problem largely</p> <p>12 doesn't rise in the Medicare or Medicaid</p> <p>13 setting. Right? We know that. It doesn't</p> <p>14 arise with regard to health exchange</p> <p>15 products because those are definitionally</p> <p>16 fully insured and the insured is going to be</p> <p>17 the client for the claims processing</p> <p>18 services.</p> <p>19 So what we're really talking</p> <p>20 about here is the category of employer and</p> <p>21 the union sponsored plans where we see this</p> <p>22 issue with the ASO and the TPA.</p> <p>23 So the first thing you have to</p> <p>24 ask yourself is how many of those plans are</p> <p>25 fully ensured. So the plan sponsor has said</p>	<p style="text-align: right;">Page 289</p> <p>1 L. Craft</p> <p>2 Now, it's not a 100%. Yes, you</p> <p>3 can find an exception where somebody went to</p> <p>4 a benefits broker -- which is a TPA, not an</p> <p>5 insurance company, a TPA -- and went out and</p> <p>6 bought insurance for their clients and there</p> <p>7 will be outliers like that. But we start</p> <p>8 with the fact that 88% are fully insured and</p> <p>9 are -- generally, the insurer can have the</p> <p>10 contracting relationship with the -- with</p> <p>11 the PBM.</p> <p>12 So what about the other 12%</p> <p>13 that are self-funding their pharmaceutical</p> <p>14 drug benefits? For that 12% that are</p> <p>15 self-funding, there's, of course, a higher</p> <p>16 probability that they're hiring an</p> <p>17 intermediary, whether there's an ASO or a</p> <p>18 TPA, that they're hiring someone to manage</p> <p>19 their benefit program.</p> <p>20 So for those 12%, we have the</p> <p>21 increased probability that what we're seeing</p> <p>22 is the intermediary in the client/carrier</p> <p>23 field.</p> <p>24 Now, most commonly, that</p> <p>25 intermediary is going to be an ASO, which is</p>

<p style="text-align: right;">Page 290</p> <p>1 L. Craft</p> <p>2 to say an insurance company that has two</p> <p>3 lines of business, it sells insurance and it</p> <p>4 sells administrative services.</p> <p>5 So the ability -- and I'm not</p> <p>6 going to go on and go on because I know you</p> <p>7 heard this this morning -- because those</p> <p>8 insurance companies have to segregate their</p> <p>9 lines of business and can readily tell you</p> <p>10 which accounts are which.</p> <p>11 So that's why I would say that</p> <p>12 this problem is one that is you peculiar to</p> <p>13 employer and union plans, is really not a</p> <p>14 major problem except when we get to</p> <p>15 self-funded plans, which are about 12% of</p> <p>16 those, and as a result, I would stand by my</p> <p>17 statement here that the ultimate payor of</p> <p>18 claims typically appears in the</p> <p>19 client/carrier field.</p> <p>20 Q. Let's talk about the exception</p> <p>21 in cases where the TPP has hired an ASO to</p> <p>22 handle its PBM contracting.</p> <p>23 I believe you said in that case</p> <p>24 the TPA or the ASO's name is going to appear</p> <p>25 in the client field; is that right?</p>	<p style="text-align: right;">Page 292</p> <p>1 L. Craft</p> <p>2 a TPA who is actually under contract with</p> <p>3 the PBM, it wouldn't be possible to look --</p> <p>4 I'm just saying to look at the client field,</p> <p>5 specifically, the client field -- and</p> <p>6 determine who the end payor TPP is, right?</p> <p>7 MR. STANOCH: Objection to</p> <p>8 form.</p> <p>9 Asked and answered.</p> <p>10 Mischaracterizes prior</p> <p>11 testimony.</p> <p>12 Incomplete hypothetical.</p> <p>13 Go ahead.</p> <p>14 A. I wouldn't want to put on</p> <p>15 blinders and look only at that one field. I</p> <p>16 would look at the other fields as well.</p> <p>17 Q. Of course. We'll take them one</p> <p>18 at a time certainly. But I just want to</p> <p>19 make sure with respect to the client field,</p> <p>20 that's where the TPA is going to show up.</p> <p>21 Right?</p> <p>22 MR. STANOCH: Same objections.</p> <p>23 A. If they are the contracting</p> <p>24 entity with the PBM, then yes.</p> <p>25 Q. The next sentence here says "In</p>
<p style="text-align: right;">Page 291</p> <p>1 L. Craft</p> <p>2 MR. STANOCH: Objection to</p> <p>3 form.</p> <p>4 Asked and answered.</p> <p>5 Mischaracterizes prior</p> <p>6 testimony.</p> <p>7 Go ahead.</p> <p>8 A. Yeah, it may. Because remember</p> <p>9 that there are self-funding suppliers, like</p> <p>10 really big ones, that contract directly</p> <p>11 with the PBM for services and they show</p> <p>12 up -- if you look up American Express in the</p> <p>13 client/carrier name, you're going to see</p> <p>14 American Express. So they're contracting</p> <p>15 directly for the PBM services.</p> <p>16 So just because a plan is</p> <p>17 self-funding doesn't mean it's using an</p> <p>18 intermediary to contract with the PBM.</p> <p>19 Q. And I understand, but I want to</p> <p>20 talk about instances where there has been an</p> <p>21 ASO or third-party administrator that has</p> <p>22 been under contract.</p> <p>23 Okay?</p> <p>24 A. Okay.</p> <p>25 Q. In that situation where there's</p>	<p style="text-align: right;">Page 293</p> <p>1 L. Craft</p> <p>2 some cases, descriptive fields in the PBM</p> <p>3 data specifically identify either fully</p> <p>4 insured or self-funded status."</p> <p>5 What's this descriptive field</p> <p>6 called? You know, every field has a name.</p> <p>7 What is this field called?</p> <p>8 A. So this variable or this value</p> <p>9 that I'm describing here could appear in the</p> <p>10 account field. It could appear in the group</p> <p>11 field. In rare instances, it could even</p> <p>12 appear in the client/carrier field. There</p> <p>13 are many ways that it may appear.</p> <p>14 So it may -- for example, the</p> <p>15 account may be described as fully or</p> <p>16 insured, which means fully insured. Either</p> <p>17 of those means fully insured or full. Or by</p> <p>18 contrast, it may say ASO or it may say TPA.</p> <p>19 It may say self, meaning self-funded. The</p> <p>20 practice with which that is recorded in the</p> <p>21 account and group fields and client name</p> <p>22 descriptions is -- I would be misleading you</p> <p>23 if I said it was completely consistent</p> <p>24 across TPAs -- I'm sorry -- across PBMs or</p> <p>25 plans. It varies.</p>

Page 294	Page 296
<p>1 L. Craft</p> <p>2 That's because that information</p> <p>3 may not be particularly useful to the client</p> <p>4 because the data is coming to them in a way</p> <p>5 that they're going to segregate it for each</p> <p>6 of their ASO or TPA clients.</p> <p>7 But what I'm saying here is</p> <p>8 that in some cases you already know because</p> <p>9 the data is explicit. You literally see the</p> <p>10 descriptor in one of those fields.</p> <p>11 Q. How often is "some cases"?</p> <p>12 A. So it -- in my experience --</p> <p>13 and it'll vary from one data set to another</p> <p>14 and one PBM to another -- but in my</p> <p>15 experience, you might see that value</p> <p>16 populated 3% of the time, something like</p> <p>17 that. It could be less.</p> <p>18 But I want to remind you that</p> <p>19 that's of the total claims volume, right? A</p> <p>20 whole bunch of that, you would never have</p> <p>21 that information because it's a health</p> <p>22 exchange plan or it's a Medicare plan or</p> <p>23 it's managed Medicaid and there's no</p> <p>24 ambiguity. They're fully insured. There's</p> <p>25 nothing to say about self or fully there.</p>	<p>1 L. Craft</p> <p>2 paragraph 68? I believe it's on page</p> <p>3 59.</p> <p>4 MR. STANOCH: Tell me if you</p> <p>5 find it.</p> <p>6 Q. All right. So Ms. Craft, I</p> <p>7 want to refer to the third sentence in this</p> <p>8 paragraph. It reads "The presence of an</p> <p>9 additional intermediary does not change or</p> <p>10 obscure the identity of the self-funded TPP,</p> <p>11 which remains fully liable for claims and</p> <p>12 whose name typically appears in PBM data</p> <p>13 alongside the ASO or TPA."</p> <p>14 My first question with respect</p> <p>15 to this sentence is what do you mean by</p> <p>16 "does not obscure the identity"?</p> <p>17 A. What I mean is what's stated in</p> <p>18 the balance of that sentence, that when you</p> <p>19 have an ASO or a TPA, it's quite common for</p> <p>20 the name of the plan sponsor to sit right</p> <p>21 next to it in the account name. Sometimes</p> <p>22 in the group name, but more commonly in the</p> <p>23 account name.</p> <p>24 So when we have both the ASO</p> <p>25 named and the self-funding plan sponsor</p>
Page 295	Page 297
<p>1 L. Craft</p> <p>2 Q. Let's go to paragraph 68 on</p> <p>3 page 443 --</p> <p>4 MR. DORNER: We've been going</p> <p>5 about an hour and a half. Dave, I</p> <p>6 think it'll be a good time to take five</p> <p>7 here. I'm going to see what I can</p> <p>8 scratch from my notes.</p> <p>9 MR. STANOCH: Ms. Craft, are</p> <p>10 you okay with that?</p> <p>11 THE WITNESS: Yes.</p> <p>12 MR. STANOCH: Let's do that.</p> <p>13 THE VIDEOGRAPHER: The time is</p> <p>14 3:10.</p> <p>15 We're going off the record.</p> <p>16 (Recess taken)</p> <p>17 THE VIDEOGRAPHER: The time is</p> <p>18 3:24.</p> <p>19 This begins media unit six.</p> <p>20 We're back on the record.</p> <p>21 MR. DORNER: I appreciate</p> <p>22 everybody's indulgence on the</p> <p>23 longer-than-intended break. Thank you</p> <p>24 very much.</p> <p>25 Can we pull up Exhibit 4,</p>	<p>1 L. Craft</p> <p>2 named, in my opinion, you have not obscured</p> <p>3 the identity of the self-funding plan</p> <p>4 sponsor. You've merely moved it to a</p> <p>5 different field.</p> <p>6 Q. Okay.</p> <p>7 So these would be in -- I guess</p> <p>8 if not in the client field, then you're</p> <p>9 saying it would be in the account or the</p> <p>10 group; is that right?</p> <p>11 A. Frequently so. I'm not saying</p> <p>12 invariably, but frequently so.</p> <p>13 Q. How frequently?</p> <p>14 A. I can't give you a precise</p> <p>15 number, but it is quite common when you see</p> <p>16 ASO and TPAs to see the self-funding plan</p> <p>17 sponsor identified in one or the other of</p> <p>18 those fields. So we see both names in</p> <p>19 parallel.</p> <p>20 Q. I want to make sure -- when we</p> <p>21 were talking during the last session, we</p> <p>22 were sort of limiting our discussion to</p> <p>23 situations where there's a self-funded TPP</p> <p>24 who has contracted with an ASO. We're still</p> <p>25 in that world for purposes of this</p>

<p style="text-align: right;">Page 298</p> <p>1 L. Craft</p> <p>2 discussion in paragraph 68, right?</p> <p>3 A. Yes. I'm still thinking about</p> <p>4 that same structure.</p> <p>5 Q. Okay.</p> <p>6 So you've said it's quite</p> <p>7 common and frequent. Do you think it's --</p> <p>8 is it more than 50% of the time that you'll</p> <p>9 get these two -- both the identity of the</p> <p>10 TPP and its ASO in the two different fields?</p> <p>11 MR. STANOCH: Objection to</p> <p>12 form.</p> <p>13 Asked and answered.</p> <p>14 A. I hesitate because sometimes</p> <p>15 instead what you get in the account field is</p> <p>16 contract numbers for the ASO contracts. So</p> <p>17 for example, contract blank, contract blank</p> <p>18 for the ASO relationships. So you may not</p> <p>19 actually see the name printed out there in</p> <p>20 that field. Of course that means the</p> <p>21 contract number is linking to the specific</p> <p>22 TPP, but you may not see the full narrative</p> <p>23 description or name.</p> <p>24 Q. Okay.</p> <p>25 So I guess -- in your</p>	<p style="text-align: right;">Page 300</p> <p>1 L. Craft</p> <p>2 A. No.</p> <p>3 Q. Okay.</p> <p>4 A. You're asking the name of the</p> <p>5 TPA or the ASO and what I'm saying is that</p> <p>6 the name of the TPA or ASO is likely to</p> <p>7 appear in the client/carrier field. If they</p> <p>8 were the entity that contracted with the</p> <p>9 PBM, then that's where that name would</p> <p>10 appear.</p> <p>11 On the contrary, it's their</p> <p>12 client, the self-funding plan sponsor, so,</p> <p>13 you know, union local whatever that appears</p> <p>14 in the account field.</p> <p>15 Q. Okay.</p> <p>16 So I flipped them?</p> <p>17 A. Yes.</p> <p>18 Q. It's possible in the PBM claims</p> <p>19 data the self-funded TPP wouldn't appear at</p> <p>20 all? The only entity to appear would be</p> <p>21 either the ASO or the third-party</p> <p>22 administrator; isn't that right?</p> <p>23 MR. STANOCH: Objection to</p> <p>24 form.</p> <p>25 Calls for speculation.</p>
<p style="text-align: right;">Page 299</p> <p>1 L. Craft</p> <p>2 experience, can you approximate how often</p> <p>3 you see the TPP and its name alongside the</p> <p>4 ASO or the TPA with whom it is contracted?</p> <p>5 MR. STANOCH: Objection to</p> <p>6 form.</p> <p>7 Asked and answered.</p> <p>8 Compound.</p> <p>9 Misstates testimony.</p> <p>10 A. I haven't tried to do that</p> <p>11 estimation. It's something I could do,</p> <p>12 looking at a large swath of PBM data, but</p> <p>13 it's not something I've attempted to</p> <p>14 calculate.</p> <p>15 Q. In this case, there's not a</p> <p>16 large swath of PBM data to look at and</p> <p>17 analyze, right?</p> <p>18 MR. STANOCH: Objection to</p> <p>19 form.</p> <p>20 A. Not produced in this case at</p> <p>21 this point in time.</p> <p>22 Q. I believe you said according to</p> <p>23 paragraph 68, you would typically find the</p> <p>24 name of the TPA or the ASO in the account</p> <p>25 field if it were there?</p>	<p style="text-align: right;">Page 301</p> <p>1 L. Craft</p> <p>2 Lacks foundation.</p> <p>3 Go ahead.</p> <p>4 A. Yes, it is possible for that to</p> <p>5 happen.</p> <p>6 Q. You've seen that instance in</p> <p>7 PBM claims data in the past?</p> <p>8 A. Rarely, but yes.</p> <p>9 Q. Well, how rarely?</p> <p>10 A. I just gave you a description a</p> <p>11 moment ago of -- and I told you that I</p> <p>12 couldn't quantify this -- but I gave you a</p> <p>13 description where the ASO insurance company</p> <p>14 appears in the client name field and then in</p> <p>15 the account field, instead of the name of</p> <p>16 the particular clients that they are</p> <p>17 self-funding claim sponsors they're working</p> <p>18 for, they have references to contract</p> <p>19 numbers that represent those clients, but</p> <p>20 without the name appearing in the data. I</p> <p>21 believe I just explained that.</p> <p>22 Q. I asked because -- I guess I'm</p> <p>23 just trying to quantify how often we might</p> <p>24 find ourselves in this situation.</p> <p>25 If there are a million</p>

<p style="text-align: right;">Page 302</p> <p>1 L. Craft</p> <p>2 prescriptions for VCDs written and 1% of the</p> <p>3 time -- let me back up.</p> <p>4 If there are a million</p> <p>5 prescriptions for VCDs that were covered by</p> <p>6 self-insured TPPs who have contracted with</p> <p>7 the TPA and ASO and even 1% of the time the</p> <p>8 TPP's name doesn't appear in the claims</p> <p>9 data, that would be 10,000 instances where</p> <p>10 we don't know who the TPP is based on the</p> <p>11 claims data, right?</p> <p>12 MR. STANOCH: Objection to</p> <p>13 form.</p> <p>14 Incomplete hypothetical.</p> <p>15 Speculative.</p> <p>16 Lacks foundation.</p> <p>17 Compound.</p> <p>18 Go ahead if you could answer.</p> <p>19 A. So the correct level of</p> <p>20 aggregation to look at this for TPP claims</p> <p>21 is at the plan level, so the payor level.</p> <p>22 We don't care how many prescriptions. It</p> <p>23 doesn't matter if it's six or if it's 100.</p> <p>24 The data is going to be consistently</p> <p>25 presented for those prescriptions that are</p>	<p style="text-align: right;">Page 304</p> <p>1 L. Craft</p> <p>2 exists, just facially based upon the PBM</p> <p>3 data.</p> <p>4 Then that ambiguity can be</p> <p>5 resolved by either getting the PBM to flag,</p> <p>6 which are ASO/TPA relationships, or by</p> <p>7 simply going directly to the -- what we know</p> <p>8 are the ASOs and TPAs out there and saying</p> <p>9 I've got this plan, this plan and this plan,</p> <p>10 which of these are for self-funded plan</p> <p>11 sponsors and by the way, give me the name of</p> <p>12 the self-funded plan sponsor.</p> <p>13 I mean, nobody -- nobody --</p> <p>14 disputes the basic fact that every single</p> <p>15 one of the ASO/TPA relationships generates</p> <p>16 data that can be and is decomposed into</p> <p>17 individual payor bills every month. That</p> <p>18 stuff is getting spun around and billed out</p> <p>19 to the TPPs every single month and nobody</p> <p>20 denies that that system works, that that</p> <p>21 system is supported by data that makes it</p> <p>22 possible to make that segregation and to</p> <p>23 generate those invoices and to direct them</p> <p>24 to the ultimate TPP reliably and rapidly in</p> <p>25 a form that can be audited.</p>
<p style="text-align: right;">Page 303</p> <p>1 L. Craft</p> <p>2 being processed for and reimbursed by that</p> <p>3 particular TPP.</p> <p>4 So your numbers are not</p> <p>5 anywhere near the reality of what's</p> <p>6 important here. So if we said, for example,</p> <p>7 that we think they're going to be 12,000</p> <p>8 plans represent -- recognizing that a lot of</p> <p>9 those are going the same payor. Right?</p> <p>10 There's, you know, the Aetna this plan and</p> <p>11 the Aetna that plan and there are different</p> <p>12 plans, but they're the same client name and</p> <p>13 payor.</p> <p>14 What we're talking about here</p> <p>15 is a very small percent of the total TPP</p> <p>16 records, i.e. payor records, that would be</p> <p>17 subject to this confusion and that is true</p> <p>18 for the reasons I previously explained that</p> <p>19 we don't have this ambiguity with this -- we</p> <p>20 typically only have this ambiguity with the</p> <p>21 employer and union claims. Most of those</p> <p>22 are fully insured, not a self-funded TPP.</p> <p>23 So only 12% of those claims are self-funded</p> <p>24 and so it's a very small bite out of the</p> <p>25 total TPP population where this ambiguity</p>	<p style="text-align: right;">Page 305</p> <p>1 L. Craft</p> <p>2 So your questions go to can I</p> <p>3 always see the identity of that TPP, the</p> <p>4 self-funding plan sponsor in just the PBM</p> <p>5 data. What I'm saying to is you no, not</p> <p>6 always. Generally, you're going to have the</p> <p>7 TPP payor. It's going to be a small percent</p> <p>8 where you don't. But where you don't,</p> <p>9 believe you me those records exist. It's</p> <p>10 not like anybody is guessing. It's not like</p> <p>11 you have to read contracts or subjectively</p> <p>12 interpret facts. You just would have a</p> <p>13 second step in data gathering. That's all.</p> <p>14 Q. You mentioned that this billing</p> <p>15 happens every month and is auditable and all</p> <p>16 of that. But the billing to the TPP in the</p> <p>17 case of a TPA or an ASO arrangement, the PBM</p> <p>18 is not billing the third-party payor in that</p> <p>19 instance. It's the TPP or the ASO that is</p> <p>20 getting reimbursed from the third-party</p> <p>21 payor, right?</p> <p>22 A. Yes. That's why I've</p> <p>23 repeatedly explained that the data that the</p> <p>24 ASO or TPA receives from the PBM needs to be</p> <p>25 sufficient for them to programmatically,</p>

<p style="text-align: right;">Page 306</p> <p>1 L. Craft</p> <p>2 electronically, automatically bill each of</p> <p>3 their underlying TPP clients. I just -- I'm</p> <p>4 saying this issue only arises when the PBM</p> <p>5 data doesn't make the relationship explicit.</p> <p>6 I'm saying in those cases, rather than</p> <p>7 throwing up our hands and saying "I guess</p> <p>8 we'll just never know," you have an</p> <p>9 objectively verifiable relationship that</p> <p>10 exists in the electronic data of that ASO or</p> <p>11 TPA and that --</p> <p>12 Q. Sorry. Go ahead.</p> <p>13 A. -- and that specifically and</p> <p>14 automatically segregates the claims and</p> <p>15 routes them to the ultimate TPP.</p> <p>16 I just -- I do not want to get</p> <p>17 lost on this point that the game's up if you</p> <p>18 can't see the relationship explicitly in the</p> <p>19 PBM data. I never said you should refuse to</p> <p>20 look at anything but PBM data.</p> <p>21 If you really think that the</p> <p>22 legal standard is it isn't good enough that</p> <p>23 the defendants know every single vial of</p> <p>24 drug that was purchased and every pill from</p> <p>25 every pharmacy on every day, if you really</p>	<p style="text-align: right;">Page 308</p> <p>1 L. Craft</p> <p>2 it need only know who the TPA or the ASO is,</p> <p>3 correct?</p> <p>4 MR. STANOCH: Objection to</p> <p>5 form.</p> <p>6 Asked and answered.</p> <p>7 Incomplete hypothetical.</p> <p>8 Compound.</p> <p>9 Ambiguous.</p> <p>10 A. Well, to send out the bill,</p> <p>11 that might be true, but it's also true that</p> <p>12 that PBM is not going to get hired unless it</p> <p>13 can provide the data to the ASO or TPA who</p> <p>14 retains it in a form that the ASO or TPA can</p> <p>15 then turn around and use for billing. So in</p> <p>16 some cases, that may mean contracts with</p> <p>17 names on them. In some cases, it may mean</p> <p>18 tell me the name of my particular ASO</p> <p>19 client -- self-funding plan sponsor -- in</p> <p>20 the account field or the group field. There</p> <p>21 are a variety of ways this can be done.</p> <p>22 I'm merely saying that if the</p> <p>23 PBM data ends up not being sufficient to</p> <p>24 resolve the identity of the self-funding</p> <p>25 plan sponsor in all cases, there's no rule</p>
<p style="text-align: right;">Page 307</p> <p>1 L. Craft</p> <p>2 think that the ability to defend against and</p> <p>3 to sustain the class requires that you</p> <p>4 assemble the actual name of the TPP where</p> <p>5 there's an ASO or TPA relationship, what I'm</p> <p>6 telling you is that's a secondary round of</p> <p>7 information gathering, but it is absolutely</p> <p>8 objectively determinable and could be done.</p> <p>9 Q. Now, I guess I want to go back</p> <p>10 to your answer that you just gave.</p> <p>11 You said that the data that the</p> <p>12 PBM -- and I'm paraphrasing here -- the data</p> <p>13 that the PBM transmits to the TPA or ASO, so</p> <p>14 that way they can do their billing, it's</p> <p>15 apparent to the TPP or the ASO who the</p> <p>16 third-party payor is, right? Obviously,</p> <p>17 that's who they're billing.</p> <p>18 Let me strike all this and work</p> <p>19 my way through this question again.</p> <p>20 Disregard all that.</p> <p>21 In the case of a self-insured</p> <p>22 plan that's retained a third-party</p> <p>23 administrator or an ASO provider, for</p> <p>24 purposes of -- for the PBM's purposes of</p> <p>25 getting reimbursed from the TPA or the ASO,</p>	<p style="text-align: right;">Page 309</p> <p>1 L. Craft</p> <p>2 that says you can't then ask that client</p> <p>3 carrier who is acting as an ASO to identify</p> <p>4 its underlying clients.</p> <p>5 Q. Okay. All right.</p> <p>6 Now, when we have a scenario</p> <p>7 where an ASO has contracted with another</p> <p>8 ASO. What is your contention as to how that</p> <p>9 appears in the additional data fields?</p> <p>10 MR. STANOCH: Objection to</p> <p>11 form.</p> <p>12 Speculative.</p> <p>13 Lacks foundation.</p> <p>14 Incomplete hypothetical.</p> <p>15 Vague.</p> <p>16 Go ahead if you can.</p> <p>17 A. Can you tell me what ASO number</p> <p>18 one is contracting with ASO number two to</p> <p>19 do? Because, as I mentioned this morning,</p> <p>20 there's a whole range of responsibilities</p> <p>21 that first-in, first-out and in many cases,</p> <p>22 those responsibilities are utterly</p> <p>23 irrelevant to this question, so --</p> <p>24 Q. Sure. Let's assume the</p> <p>25 agreement is for claims adjudication.</p>

<p style="text-align: right;">Page 310</p> <p>1 L. Craft</p> <p>2 MR. STANOCH: Same objections.</p> <p>3 A. Uh-huh. So --</p> <p>4 Q. Yes.</p> <p>5 A. An ASO contracts with another</p> <p>6 ASO to contract for claims adjudication?</p> <p>7 Q. Yes.</p> <p>8 A. I'm not familiar with a</p> <p>9 contract structure of that type or a</p> <p>10 business relationship structure of that</p> <p>11 type.</p> <p>12 Q. Okay.</p> <p>13 A. Can you point me to real-world</p> <p>14 examples of that because that's --</p> <p>15 Q. I'm not professing to be an</p> <p>16 expert in those sorts of relationships, so</p> <p>17 let me ask it another way.</p> <p>18 Let's say an ASO -- let's do</p> <p>19 TPA.</p> <p>20 A TPA has contracted with</p> <p>21 another TPA who has, in turn, contracted</p> <p>22 with the third-party payor. The TPA, as</p> <p>23 part of their contractual arrangement,</p> <p>24 involves reimbursement from one third-party</p> <p>25 administrator to the next, which then goes</p>	<p style="text-align: right;">Page 312</p> <p>1 L. Craft</p> <p>2 the broker might show up in there.</p> <p>3 Maybe then I'm thinking that</p> <p>4 your example might be an attempt to describe</p> <p>5 a relationship where that broker or benefit</p> <p>6 advisor then says hey, you should really</p> <p>7 self-fund your plans and so I'm going to</p> <p>8 advise you to contract with Blue Shield of</p> <p>9 Louisiana as your ASO and I'm going to bring</p> <p>10 a bunch of clients to Blue Shield of</p> <p>11 Louisiana in an ASO capacity and Blue Shield</p> <p>12 of Louisiana is going to handle all your</p> <p>13 business for all of you and it's going to be</p> <p>14 a great deal. So you're going to pay your</p> <p>15 own claims, but we're going to use Blue</p> <p>16 Shield of Louisiana.</p> <p>17 In that situation, it's far</p> <p>18 more likely that Blue Shield of Louisiana is</p> <p>19 going to use Express Scripts, which it likes</p> <p>20 to use for all of its business, than that</p> <p>21 it's going to say "Hey, benefit advisor,</p> <p>22 broker, coach on human relations benefits in</p> <p>23 the office place, you go out and contract</p> <p>24 with the PBM." That's far less likely.</p> <p>25 So I'm wondering if that is the</p>
<p style="text-align: right;">Page 311</p> <p>1 L. Craft</p> <p>2 to the PBM.</p> <p>3 In that instance, how would</p> <p>4 these -- what would the client and</p> <p>5 accounting group field say with respect to</p> <p>6 the identities of the TPAs and the TPP?</p> <p>7 MR. STANOCH: Objection to</p> <p>8 form.</p> <p>9 Incomplete hypothetical.</p> <p>10 Lacks foundation.</p> <p>11 Speculative.</p> <p>12 Ambiguous.</p> <p>13 Borderline unintelligible.</p> <p>14 But go ahead, Ms. Craft.</p> <p>15 A. I'm trying to think of a</p> <p>16 scenario that might actually happen that</p> <p>17 would be analogous to what you're describing</p> <p>18 and I'm using my imagination here because</p> <p>19 this is not a structure that I'm familiar</p> <p>20 with seeing, but it could, in theory, happen</p> <p>21 that you would hire a benefit administrator</p> <p>22 and advisor who would go out and -- so, for</p> <p>23 example, a broker, which I think is the</p> <p>24 example that Mr. Kosty uses in his report.</p> <p>25 He says oh, you could hire a broker and then</p>	<p style="text-align: right;">Page 313</p> <p>1 L. Craft</p> <p>2 kind of scenario -- I saw nothing that I</p> <p>3 could identify -- that I could clearly</p> <p>4 understand in Mr. Kosty's report about this</p> <p>5 speculation of layering of intermediaries on</p> <p>6 top of each other, so I have a little</p> <p>7 difficulty responding to it and determining</p> <p>8 whether it presents any actual real world</p> <p>9 complications or not or whether you have</p> <p>10 your ASO, who is handling all your claims,</p> <p>11 contracting with your PBM and then we're</p> <p>12 back to go.</p> <p>13 Q. In paragraph 68, you say that</p> <p>14 PBMs should be expected to know what their</p> <p>15 client's contractual arrangements are.</p> <p>16 What are you offering to actual</p> <p>17 support that statement?</p> <p>18 MR. STANOCH: Objection to</p> <p>19 form.</p> <p>20 Go ahead.</p> <p>21 A. That there are multiple reasons</p> <p>22 for wanting to know whether the contracting</p> <p>23 entity is acting in a representative</p> <p>24 capacity or is the actual payor.</p> <p>25 The first thing is that if</p>

<p style="text-align: right;">Page 314</p> <p>1 L. Craft</p> <p>2 they're the actual payor, you're going to</p> <p>3 care a whole lot more about their financial</p> <p>4 wherewithal because they're the one and only</p> <p>5 source of payment for the amounts that the</p> <p>6 PBM is going to be delivering to the</p> <p>7 pharmacies and Mr. Kosty gives this the back</p> <p>8 of his hand by saying yeah, but sometimes</p> <p>9 they set up an escrow and so nobody worries</p> <p>10 because you know the money is there because</p> <p>11 it's escrowed.</p> <p>12 The reason they set up an</p> <p>13 escrow is because they're concerned that the</p> <p>14 payment flow may not be timely without the</p> <p>15 escrow. So PBMs make decisions about credit</p> <p>16 risk by knowing who is responsible to pay</p> <p>17 them. When they're talking about a big</p> <p>18 insurance company that is -- is doing both</p> <p>19 ASO business and fully insured business, the</p> <p>20 client itself is going to ultimately need to</p> <p>21 have the data structured and set up so that</p> <p>22 it can bill to two, four, 100 different</p> <p>23 clients.</p> <p>24 So the idea that the PBM would</p> <p>25 be blind to that and would not be party to</p>	<p style="text-align: right;">Page 316</p> <p>1 L. Craft</p> <p>2 not privy to the underlying payor identity.</p> <p>3 I don't think that is what I said here.</p> <p>4 The sentence that you were</p> <p>5 pointing me to is the following. On page</p> <p>6 45, in paragraph 68, I say "However, PBM's</p> <p>7 shouldn't be expected to know that capacity</p> <p>8 in which their clients are contracting,</p> <p>9 whether on behalf of themselves or as an ASO</p> <p>10 TPA for a self-funding TPP."</p> <p>11 I did not say, as your most</p> <p>12 recent question seems to imply, that the PBM</p> <p>13 would necessarily need the names of each of</p> <p>14 those ASO clients in order to do its work.</p> <p>15 Q. Now, it's true that TPAs, at</p> <p>16 least in some cases, are incentivized not to</p> <p>17 provide their clients' identities to the</p> <p>18 PBM, so that way the PBM can't go around the</p> <p>19 TPA as the middleman and market its business</p> <p>20 services directly to the TPP; isn't that</p> <p>21 right?</p> <p>22 MR. STANOCH: Objection to</p> <p>23 form.</p> <p>24 A. Well, I certainly saw that</p> <p>25 Mr. Kosty said that. I have not seen that</p>
<p style="text-align: right;">Page 315</p> <p>1 L. Craft</p> <p>2 setting up the data so that it can be used</p> <p>3 in that way is, to me, incongruous.</p> <p>4 Q. But isn't there a different --</p> <p>5 the PBM can have its data set up in a</p> <p>6 certain way so as to allow an ASO or a TPA</p> <p>7 to bill its clients, but that doesn't mean</p> <p>8 that the PBM itself is going to know who the</p> <p>9 TPA and ASO's clients are; isn't that right?</p> <p>10 MR. STANOCH: Objection.</p> <p>11 Q. Let me preface my question --</p> <p>12 let me withdraw me question and re-ask it in</p> <p>13 one -- with one modification.</p> <p>14 So the PBM can have its data</p> <p>15 set up in a certain way so as to allow an</p> <p>16 ASO or a TPA to bill its clients, but that</p> <p>17 doesn't mean in all instances that the PBM</p> <p>18 itself is going to know who the TPA or the</p> <p>19 ASO's clients are; isn't that true?</p> <p>20 MR. STANOCH: Objection to</p> <p>21 form.</p> <p>22 Incomplete hypothetical.</p> <p>23 Vague.</p> <p>24 A. Sure, Mr. Dorner, it's possible</p> <p>25 that there's some instances where a PBM is</p>	<p style="text-align: right;">Page 317</p> <p>1 L. Craft</p> <p>2 in operation, but it's a plausible theory</p> <p>3 that there might be reasons why an ASO of a</p> <p>4 large insurance company, for example,</p> <p>5 doesn't want to necessarily name all of its</p> <p>6 ASO clients. There wasn't an illogical</p> <p>7 proposition on Mr. Kosty's part. I've not</p> <p>8 seen that dynamic at work, so I certainly</p> <p>9 can't confirm that.</p> <p>10 Q. Right.</p> <p>11 But then again, you haven't</p> <p>12 worked for a PBM before; is that true?</p> <p>13 A. That is true.</p> <p>14 Q. You have never worked for an</p> <p>15 insurance company, whether in a fully</p> <p>16 insured or ASO role, correct?</p> <p>17 A. That's true.</p> <p>18 Q. You've never worked for a --</p> <p>19 let me check my -- you've never worked for a</p> <p>20 third-party administrator?</p> <p>21 A. That's also true.</p> <p>22 You skipped retail pharmacy. I</p> <p>23 also haven't worked for a retail pharmacy.</p> <p>24 Q. I have a feeling, Ms. Craft,</p> <p>25 you've been asked these questions before.</p>

<p style="text-align: right;">Page 318</p> <p>1 L. Craft</p> <p>2 All right. I appreciate your candor.</p> <p>3 So Ms. Craft, we've testified</p> <p>4 quite a bit about what can be done, what</p> <p>5 data sources are out there.</p> <p>6 Have you ever actually</p> <p>7 identified class members in a medical</p> <p>8 monitoring -- I want to focus on medical</p> <p>9 monitoring right now.</p> <p>10 Have you ever actually</p> <p>11 identified class members in a medical</p> <p>12 monitoring case based on the level of their</p> <p>13 alleged lifetime cumulative exposure to a</p> <p>14 pharmaceutical impurity?</p> <p>15 MR. STANOCH: Objection.</p> <p>16 Asked and answered.</p> <p>17 Vague.</p> <p>18 Go ahead.</p> <p>19 A. I have never worked on a</p> <p>20 medical monitoring class. As I explained to</p> <p>21 you earlier, the procedure is very similar</p> <p>22 to what I have done in other cases, which is</p> <p>23 to say to compile the historical record of</p> <p>24 prescriptions for individual members and</p> <p>25 track those over time, which I understand to</p>	<p style="text-align: right;">Page 320</p> <p>1 L. Craft</p> <p>2 question, so let me clarify mine.</p> <p>3 In a case that's seeking</p> <p>4 monetary damages for the payment associated</p> <p>5 with a prescription drug, have you ever</p> <p>6 actually carried the methodology you propose</p> <p>7 in your report through to produce a list of</p> <p>8 class members with exclusions applied?</p> <p>9 Let me back up.</p> <p>10 Even with class members.</p> <p>11 Forget about exclusion.</p> <p>12 MR. STANOCH: Objection to</p> <p>13 form.</p> <p>14 Hopelessly convoluted.</p> <p>15 Go ahead, if you could try.</p> <p>16 A. As I think I testified a couple</p> <p>17 times today, I have never reached the point</p> <p>18 in a case in which I've been engaged where</p> <p>19 it was necessary to compile a final list.</p> <p>20 Some courts say that's an utter and complete</p> <p>21 waste of time. It's not a necessary process</p> <p>22 at all and what the court wants to know is</p> <p>23 the feasibility of doing so. I have not had</p> <p>24 a case where, for example, all of the, say,</p> <p>25 top six PBMs have produced their data in a</p>
<p style="text-align: right;">Page 319</p> <p>1 L. Craft</p> <p>2 be the mechanism proposed to be used here</p> <p>3 for qualifying in the medical monitoring</p> <p>4 class.</p> <p>5 Q. And that was in the antitrust</p> <p>6 suit I believe you said, right?</p> <p>7 A. Yes.</p> <p>8 Q. Have you ever actually</p> <p>9 identified class members in a consumer</p> <p>10 economic loss class action involving</p> <p>11 pharmaceutical products?</p> <p>12 MR. STANOCH: Objection to</p> <p>13 form.</p> <p>14 And I just caution you about</p> <p>15 potential privilege consulting</p> <p>16 protective orders.</p> <p>17 A. Well, you've asked if I've</p> <p>18 identified consumers in an economic loss</p> <p>19 claim. I don't know what you call an</p> <p>20 economic loss claim, but I think that</p> <p>21 overcharge cases are economic loss claims in</p> <p>22 the antitrust forum.</p> <p>23 What do you mean by economic</p> <p>24 loss claim?</p> <p>25 Q. Sure. I guess that's a fair</p>	<p style="text-align: right;">Page 321</p> <p>1 L. Craft</p> <p>2 single piece of litigation.</p> <p>3 So if what you mean when you</p> <p>4 ask have I ever prepared a list, I mean,</p> <p>5 I've certainly counted consumers in</p> <p>6 subgroups of classes involving payments for</p> <p>7 prescription drugs, but I think you're</p> <p>8 asking the bigger question: Did you ever</p> <p>9 come up with a complete list of consumers</p> <p>10 and TPPs in a case that involved a claim for</p> <p>11 money damages and the answer is I've never</p> <p>12 been required to finalize that process</p> <p>13 because it's never been found by a court to</p> <p>14 be necessary.</p> <p>15 MR. DORNER: What I'd like to</p> <p>16 do is check with other counsel who are</p> <p>17 listening to see if they'd like to take</p> <p>18 a break to prepare any questions,</p> <p>19 rather than -- or just go straight into</p> <p>20 them.</p> <p>21 So I guess I'll ask any</p> <p>22 co-counsel right now would you like to</p> <p>23 take a quick five to assemble your</p> <p>24 thoughts or if you have questions --</p> <p>25 MS. ANDRAS: I could definitely</p>

<p style="text-align: right;">Page 322</p> <p>1 L. Craft</p> <p>2 use about five minutes.</p> <p>3 MR. DORNER: Okay. All right.</p> <p>4 Dave, I think I wrapped up my</p> <p>5 primary examination here, so let's take</p> <p>6 a quick five and let any other</p> <p>7 co-counsel get organized and we'll go</p> <p>8 back on for the last little bit here.</p> <p>9 THE VIDEOGRAPHER: Time is</p> <p>10 3:58.</p> <p>11 We're going off the record.</p> <p>12 (Recess taken)</p> <p>13 THE VIDEOGRAPHER: The time is</p> <p>14 4:06.</p> <p>15 We are back on the record.</p> <p>16 EXAMINATION BY</p> <p>17 MS. ANDRAS:</p> <p>18 Q. Hi, Ms. Craft. My name is</p> <p>19 Tiffany Andras. I represent Teva</p> <p>20 Pharmaceuticals in this case. I have a few</p> <p>21 questions -- a couple minutes -- to ask you</p> <p>22 today.</p> <p>23 Earlier, you testified that</p> <p>24 your opinions in this case referred to</p> <p>25 ascertainability and numerosity.</p>	<p style="text-align: right;">Page 324</p> <p>1 L. Craft</p> <p>2 form.</p> <p>3 Outside the scope.</p> <p>4 A. Yes, I've not been asked to</p> <p>5 form any opinion about what the proper</p> <p>6 measure of damages is and I'm expressing no</p> <p>7 such opinion.</p> <p>8 Q. You're not offering an opinion</p> <p>9 that economic damages can be proven on a</p> <p>10 class wide basis, are you?</p> <p>11 MR. STANOCH: Objection to form</p> <p>12 to the extent that it touches on the</p> <p>13 aspects of her report.</p> <p>14 Go ahead, Ms. Craft.</p> <p>15 A. To the extent that that opinion</p> <p>16 involves the question is there data showing</p> <p>17 how much consumers and TPPs paid for these</p> <p>18 products that are challenged during the</p> <p>19 class period, I am definitely offering an</p> <p>20 opinion that that data exists. That's</p> <p>21 fundamental to my ascertainability opinions.</p> <p>22 So whether that's the right</p> <p>23 calculus for damages, I express no opinion,</p> <p>24 but I am definitely telling you that that</p> <p>25 data exists to -- if out-of-pocket payments</p>
<p style="text-align: right;">Page 323</p> <p>1 L. Craft</p> <p>2 Is that correct?</p> <p>3 MR. STANOCH: Objection to</p> <p>4 form.</p> <p>5 Misstates previous testimony.</p> <p>6 Go ahead.</p> <p>7 A. They do pertain to</p> <p>8 ascertainability and numerosity. Yes,</p> <p>9 there's more to them.</p> <p>10 That was the long colloquy</p> <p>11 between myself and Mr. Dorner about the</p> <p>12 specific opinions being, I think, related to</p> <p>13 ascertainability. But -- so yeah, it's</p> <p>14 connected to ascertainability and</p> <p>15 numerosity.</p> <p>16 Q. You're not offering an opinion</p> <p>17 here on the appropriate measure of damages</p> <p>18 for the legal claims that are being pursued</p> <p>19 by the plaintiffs in this case, right?</p> <p>20 A. I am not.</p> <p>21 Q. So it is not your opinion that</p> <p>22 the amounts paid by potential class members</p> <p>23 are the proper measures of damages for</p> <p>24 economic loss in this case?</p> <p>25 MR. STANOCH: Objection to</p>	<p style="text-align: right;">Page 325</p> <p>1 L. Craft</p> <p>2 is the right measure, they are recorded in</p> <p>3 the data.</p> <p>4 Q. You're not offering an opinion</p> <p>5 that if there's a different measure of</p> <p>6 damages applied that is not the</p> <p>7 out-of-pocket amount for a class member,</p> <p>8 your opinion is not that those damages</p> <p>9 figures would be included in the available</p> <p>10 data?</p> <p>11 MR. STANOCH: Objection.</p> <p>12 Ambiguous.</p> <p>13 Outside the scope.</p> <p>14 Incomplete hypothetical.</p> <p>15 Go ahead, Ms. Craft, if you</p> <p>16 can.</p> <p>17 A. I can't answer that without</p> <p>18 knowing what the alternative measure would</p> <p>19 be.</p> <p>20 Q. As you sit here today, your</p> <p>21 opinion and the work that you've done in</p> <p>22 this case, you have not done an analysis</p> <p>23 that would account for any alternative</p> <p>24 measures of economic damages other than</p> <p>25 amounts paid by potential class members,</p>

<p style="text-align: right;">Page 326</p> <p>1 L. Craft</p> <p>2 correct?</p> <p>3 MR. STANOCH: Objection to</p> <p>4 form.</p> <p>5 Go ahead.</p> <p>6 A. That's true. I would agree</p> <p>7 with that, Ms. Andras.</p> <p>8 Q. Earlier, Drew I think asked you</p> <p>9 to define the word "programmatic" as you've</p> <p>10 been using it to describe your</p> <p>11 methodologies.</p> <p>12 I believe your testimony was</p> <p>13 that it was something that's executed</p> <p>14 through software programming.</p> <p>15 Is that an accurate description</p> <p>16 of your testimony?</p> <p>17 MR. STANOCH: Objection.</p> <p>18 A. That's what I recall having</p> <p>19 said.</p> <p>20 Q. Is there anything proprietary</p> <p>21 about any of the services or software</p> <p>22 programming that is offered by On Point?</p> <p>23 MR. STANOCH: Objection to</p> <p>24 form.</p> <p>25 Ambiguous.</p>	<p style="text-align: right;">Page 328</p> <p>1 L. Craft</p> <p>2 case and not in cases like this. I have --</p> <p>3 I may have used proprietary software in a</p> <p>4 few instances I could think of, but they're</p> <p>5 absolutely not germane to this situation.</p> <p>6 Q. I want to talk about the</p> <p>7 medical monitoring class.</p> <p>8 In your report, you talk about</p> <p>9 constructing a consumption record for</p> <p>10 individual class members based on the</p> <p>11 pharmacy data.</p> <p>12 Is that right?</p> <p>13 MR. STANOCH: Objection to</p> <p>14 form.</p> <p>15 Asked and answered.</p> <p>16 Go ahead.</p> <p>17 A. Actually, I talk about that</p> <p>18 both for the pharmacy data and the PBM data.</p> <p>19 Q. Okay.</p> <p>20 We can collectively refer to</p> <p>21 that as the claims data for purposes of</p> <p>22 these questions.</p> <p>23 Is that fair?</p> <p>24 A. Sure.</p> <p>25 Q. There are various minimum</p>
<p style="text-align: right;">Page 327</p> <p>1 L. Craft</p> <p>2 MS. ANDRAS: I'll ask it a</p> <p>3 different way.</p> <p>4 Q. Does On Point Analytics use any</p> <p>5 proprietary software programming to conduct</p> <p>6 its analysis?</p> <p>7 MR. STANOCH: Objection to</p> <p>8 form.</p> <p>9 Ambiguous.</p> <p>10 Go ahead.</p> <p>11 A. We use standard software</p> <p>12 packages, most typically Status, sometimes</p> <p>13 Sass. We run our work on standard</p> <p>14 software -- statistical software packages so</p> <p>15 that we can show that work and communicate</p> <p>16 that work in our expert reports and so that</p> <p>17 it can be vetted by opposing experts.</p> <p>18 Q. Okay.</p> <p>19 So there's no proprietary</p> <p>20 software that On Point necessarily uses to</p> <p>21 perform its calculations when it's engaged</p> <p>22 in litigation services like this?</p> <p>23 MR. STANOCH: Objection to</p> <p>24 form.</p> <p>25 A. Well, certainly not in this</p>	<p style="text-align: right;">Page 329</p> <p>1 L. Craft</p> <p>2 criteria that plaintiffs have proposed for</p> <p>3 inclusion in the medical monitoring class</p> <p>4 based on dosage, length of time of</p> <p>5 consumption and manufacturer of the API.</p> <p>6 Is that your understanding?</p> <p>7 MR. STANOCH: Objection to</p> <p>8 form.</p> <p>9 Misstates the report.</p> <p>10 Facts.</p> <p>11 Go ahead.</p> <p>12 A. When you say length of time of</p> <p>13 consumption, what do you mean?</p> <p>14 MS. ANDRAS: Well, can we pull</p> <p>15 up the document that was marked as the</p> <p>16 last exhibit? I think it's Exhibit M</p> <p>17 in the public share folder.</p> <p>18 MR. DORNER: This is Drew</p> <p>19 Dörner.</p> <p>20 That's going to be Exhibit 7 as</p> <p>21 it was marked if you're referring to</p> <p>22 the class definitions, Tiffany.</p> <p>23 MS. ANDRAS: Yes, class</p> <p>24 definitions. It's on page 69 of</p> <p>25 Exhibit 7.</p>

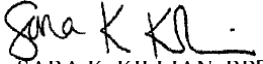
Page 330	Page 332
<p>1 L. Craft</p> <p>2 THE VIDEOGRAPHER: PDF page 69?</p> <p>3 MS. ANDRAS: Yes. Okay.</p> <p>4 If you could scroll down a</p> <p>5 little bit, so we could get the last</p> <p>6 paragraph -- there we go.</p> <p>7 Q. All right. Ms. Craft, do you</p> <p>8 see where the paragraph here -- last</p> <p>9 paragraph on page one of what we're looking</p> <p>10 at going to -- through the next page that</p> <p>11 has the thresholds for inclusion in the</p> <p>12 medical monitoring class?</p> <p>13 A. I do and none of them refer to</p> <p>14 a duration of time. They refer to</p> <p>15 quantities. So taking 64 months or taking</p> <p>16 32 months of a product doesn't mean taking</p> <p>17 it over 32 months, as I understand it, or</p> <p>18 over 64 months.</p> <p>19 The factor is -- the criteria</p> <p>20 is how much of the product is consumed by</p> <p>21 the consumer. Right? Not the duration over</p> <p>22 which they took it. This is -- when we talk</p> <p>23 about 64 months, we're talking here about</p> <p>24 quantities. So 30 days is a month supply.</p> <p>25 That's how I interpreted this at any rate.</p>	<p>1 L. Craft</p> <p>2 be some consumers who bought the challenged</p> <p>3 products but did not purchase sufficient</p> <p>4 quantities of them in the class period to</p> <p>5 qualify in accordance with this definition.</p> <p>6 Q. Well, my question was a little</p> <p>7 bit different. It was specific to different</p> <p>8 manufacturers.</p> <p>9 So do you agree that an</p> <p>10 individual class member may have taken</p> <p>11 valsartan that was manufactured by different</p> <p>12 defendants?</p> <p>13 A. Yes, that is possible.</p> <p>14 Q. You agree that also that</p> <p>15 individual class member may have taken</p> <p>16 valsartan at different dosages?</p> <p>17 A. Yes.</p> <p>18 Q. So accordingly, if you're going</p> <p>19 to construct a consumption record, that</p> <p>20 would require an analysis of potentially</p> <p>21 multiple NDCs, including the quantities</p> <p>22 fills for those NDCs, to establish whether</p> <p>23 they meet these criteria.</p> <p>24 Correct?</p> <p>25 MR. STANOCH: Objection to</p>
Page 331	Page 333
<p>1 L. Craft</p> <p>2 Q. Okay.</p> <p>3 A. So, for example, I could take</p> <p>4 six months of the product in 2014, take</p> <p>5 another six months in 2016 and take another</p> <p>6 six months in 2018 and that would be 18</p> <p>7 months, even though that's not the duration</p> <p>8 over which those pills are taken.</p> <p>9 Q. Right. Sorry. I guess I did</p> <p>10 not mean to ask about consecutive</p> <p>11 consumption, if that's what you were</p> <p>12 interpreting my -- where I was going with</p> <p>13 that. I don't think it's any matter.</p> <p>14 Do you agree that some class</p> <p>15 members may have taken particular</p> <p>16 manufacturers' product for periods of time</p> <p>17 that are less than the quantities for these</p> <p>18 minimum thresholds put forth for lifetime</p> <p>19 cumulative threshold?</p> <p>20 MR. STANOCH: Objection to</p> <p>21 form.</p> <p>22 They are class members if they</p> <p>23 did this, so if they didn't do --</p> <p>24 objection to form.</p> <p>25 A. Yes, I imagine that there will</p>	<p>1 L. Craft</p> <p>2 form.</p> <p>3 Misstates class definition.</p> <p>4 Misstates testimony and</p> <p>5 opinions.</p> <p>6 Go ahead.</p> <p>7 A. Yes, but all of those data</p> <p>8 elements are present. We always have in the</p> <p>9 data not only the label name of the drug,</p> <p>10 but we have its dosage strength and we have</p> <p>11 the days of supply that are being purchased.</p> <p>12 So the fact that -- if your point is that</p> <p>13 somebody might have taken less than the</p> <p>14 requisite supply, yes, that is a</p> <p>15 possibility.</p> <p>16 If someone may have switched</p> <p>17 products and taken one or the other at</p> <p>18 different periods of time, that is also</p> <p>19 possible. But the fact that we need to look</p> <p>20 at the dosage and days of supply is not in</p> <p>21 any way problematic. That's automatically</p> <p>22 present in the data.</p> <p>23 Q. Okay.</p> <p>24 Just to break that down a</p> <p>25 little bit, I want to be a little more</p>

<p style="text-align: right;">Page 334</p> <p>1 L. Craft</p> <p>2 specific about the data that you're talking</p> <p>3 about, that you need to determine if an</p> <p>4 individual met the criteria.</p> <p>5 So we need the NDCs numbers,</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. We need the quantity that was</p> <p>9 filled for each NDC number, right?</p> <p>10 A. That's right.</p> <p>11 Q. And we need either the name of</p> <p>12 the individual or a unique identifier that</p> <p>13 could be used to isolate that individual's</p> <p>14 consumption record, right?</p> <p>15 A. Yes.</p> <p>16 Q. And that data is present in the</p> <p>17 information that you've reviewed that's been</p> <p>18 produced in this litigation, correct?</p> <p>19 A. Yes. We have the</p> <p>20 identification number but not the name, the</p> <p>21 consumers. And we have one entity, one</p> <p>22 retailer who didn't produce the</p> <p>23 identification names, numbers either. But</p> <p>24 they are present, so yes, your description</p> <p>25 is correct.</p>	<p style="text-align: right;">Page 336</p> <p>1 L. Craft</p> <p>2 for inclusion in the class?</p> <p>3 MR. STANOCH: Objection to</p> <p>4 form.</p> <p>5 Incomplete hypothetical.</p> <p>6 Foundation.</p> <p>7 Go ahead if you can.</p> <p>8 A. So the first thing you do is</p> <p>9 you schedule all those purchases for the</p> <p>10 consumer, which is -- by schedule, I mean</p> <p>11 this as a simple programmatic exercise.</p> <p>12 We've linked the records for the consumer.</p> <p>13 So then we know that we've got X number of</p> <p>14 months of one product, X number of another.</p> <p>15 You would -- for the hypothetical I believe</p> <p>16 that you just described, you would need to</p> <p>17 know who the API manufacturer was. So you</p> <p>18 would need to append the API manufacturer</p> <p>19 identity to those records, which you can use</p> <p>20 by walking backwards to the NDC.</p> <p>21 So we've added one field to</p> <p>22 what's already there, which is who the</p> <p>23 manufacturer is. Then we've got our total</p> <p>24 schedule of how many months of each at each</p> <p>25 dosage the consumer has consumed. And I</p>
<p style="text-align: right;">Page 335</p> <p>1 L. Craft</p> <p>2 Q. At least for the MSP data, that</p> <p>3 claims data did include names of individual</p> <p>4 insureds, right?</p> <p>5 A. Yes, it did.</p> <p>6 Q. Okay.</p> <p>7 So I want to walk through an</p> <p>8 example with you of a hypothetical class</p> <p>9 member.</p> <p>10 So looking at the amounts and</p> <p>11 keeping those in mind here with the relative</p> <p>12 LCT thresholds that plaintiffs have put</p> <p>13 forward, if there was a consumer who started</p> <p>14 taking seven months -- they started taking</p> <p>15 valsartan -- seven months of ZHP's 40</p> <p>16 milligram valsartan product, but then her</p> <p>17 physician increases her dosage to</p> <p>18 80 milligrams for six months and let's say</p> <p>19 half of those fills are from Mylan and half</p> <p>20 are from Aurobindo, which correspond to</p> <p>21 different lengths of usage, according to</p> <p>22 this threshold formula, Plaintiff's Exhibit</p> <p>23 4, how do you construct that consumption</p> <p>24 record in a systematic way to determine</p> <p>25 whether that individual meets the threshold</p>	<p style="text-align: right;">Page 337</p> <p>1 L. Craft</p> <p>2 wasn't able - I apologize -- to clearly</p> <p>3 track your example against these four sets</p> <p>4 of alternatives.</p> <p>5 So I have the sense that you're</p> <p>6 asking what if they don't qualify within any</p> <p>7 of these four examples individually, but</p> <p>8 they've got half of example D and half of</p> <p>9 example B or something of that sort. Is</p> <p>10 that what you're asking?</p> <p>11 Q. Correct.</p> <p>12 How would you in a systematic</p> <p>13 way determine whether that person met the</p> <p>14 cumulative threshold. I consider myself</p> <p>15 pretty good at Excel -- I was a former</p> <p>16 financial analyst -- and I couldn't come up</p> <p>17 with a good methodology of doing this. So</p> <p>18 I'm curious to see what your proposed</p> <p>19 methodology would be for the specific</p> <p>20 examples in terms of formula and things like</p> <p>21 that. Very specific.</p> <p>22 MR. STANOCH: Objection to</p> <p>23 form -- objection to form to the</p> <p>24 colloquy with the question and the</p> <p>25 incomplete hypothetical.</p>

<p style="text-align: right;">Page 338</p> <p>1 L. Craft</p> <p>2 Ambiguous.</p> <p>3 Go ahead, Ms. Craft.</p> <p>4 A. Well, so I mean you can just</p> <p>5 literal apply these rules. Right? So let's</p> <p>6 just look at A. At a dose of</p> <p>7 320 milligrams, the class member needs to</p> <p>8 have taken a combination of three months of</p> <p>9 ZHP API or 18 months of Hetero API or 54</p> <p>10 months of Mylan or Aurobindo API.</p> <p>11 So if I literally apply that</p> <p>12 rule, I only look at dosages of</p> <p>13 320 milligrams. So I look at the consumer's</p> <p>14 purchases and I say which of these are</p> <p>15 320 milligrams and I then look to see</p> <p>16 whether we've got at least three months</p> <p>17 where the API on those 320 milligram dosages</p> <p>18 was ZHP or whether we've got 18 months where</p> <p>19 there was Hetero API or whether there was 54</p> <p>20 months of Mylan and/or Aurobindo API.</p> <p>21 So now we've treated all of the</p> <p>22 options for qualification under subpart A.</p> <p>23 Using the data that I just described that</p> <p>24 gives us the number of days supply for each</p> <p>25 purchase at a particular dosage strength,</p>	<p style="text-align: right;">Page 340</p> <p>1 L. Craft</p> <p>2 scale -- hundreds of thousands of claims on</p> <p>3 prescription fills -- how are you going to</p> <p>4 determine this on a mass scale -- if we're</p> <p>5 looking at an individual consumer's record,</p> <p>6 it is pretty complicated anyway to figure it</p> <p>7 out, but, you know, you could do it after</p> <p>8 some work. We have all done it for the</p> <p>9 medical monitoring for plaintiffs here and</p> <p>10 it took some work.</p> <p>11 How do you take it from that</p> <p>12 individual level analysis and blow it out on</p> <p>13 a systematic claims data with hundreds of</p> <p>14 thousands of lines of code and, you know, 50</p> <p>15 of them could be towards one plaintiff</p> <p>16 alone? What is that step and how does that</p> <p>17 translate?</p> <p>18 MR. STANOCH: Objection to</p> <p>19 form.</p> <p>20 Incomplete hypothetical.</p> <p>21 Compound.</p> <p>22 Vague.</p> <p>23 Ambiguous.</p> <p>24 I think I heard a concession of</p> <p>25 numerosity in my mind, but go ahead,</p>
<p style="text-align: right;">Page 339</p> <p>1 L. Craft</p> <p>2 appended with the identity of the API</p> <p>3 manufacturer, you can flag each one of the</p> <p>4 months of therapy that was purchased. So</p> <p>5 for every month, it is going to be</p> <p>6 classified in one of those categories or is</p> <p>7 not falling within one of these categories.</p> <p>8 So I'm not -- if I just look at</p> <p>9 example A here, I'm not sure what the</p> <p>10 complexity is. Every month is classified</p> <p>11 based on its -- every month of treatment is</p> <p>12 classified based upon who made the API in</p> <p>13 this case -- right? -- and what the dosage</p> <p>14 strength was. So I've got two variables.</p> <p>15 Was the API made by ZHP or Aurobindo and</p> <p>16 then I'm simply summing up the months of</p> <p>17 that therapy, so -- then I go on to B. If I</p> <p>18 didn't make it with A, now I'm going to look</p> <p>19 at the number of months that a given</p> <p>20 consumer had 160 milligram dose --</p> <p>21 Q. Can I interrupt you right</p> <p>22 there, Ms. Craft?</p> <p>23 It's this step in the equation</p> <p>24 that I'm really wanting to know more</p> <p>25 specifically about, is how on a massive</p>	<p style="text-align: right;">Page 341</p> <p>1 L. Craft</p> <p>2 Ms. Craft.</p> <p>3 A. So the truth is that that is a</p> <p>4 really hard exercise if you sit there and</p> <p>5 read individual claim records and try to put</p> <p>6 them into Excel. It is not a hard exercise</p> <p>7 to do if all you're doing is recounting</p> <p>8 every claim to add the -- to add the API</p> <p>9 manufacturer. Okay? So that's all I'm</p> <p>10 doing here. I'm adding the API</p> <p>11 manufacturer, just using example one.</p> <p>12 So that's pretty easy because</p> <p>13 it's NDC based. Right? So we've just added</p> <p>14 the identity of the API manufacturer and now</p> <p>15 all we're doing is writing code that says</p> <p>16 for each uniquely identified consumer, how</p> <p>17 many months of 320 milligram ZHP API did</p> <p>18 they have, how many months of Hetero API did</p> <p>19 they have.</p> <p>20 I mean, this data is all</p> <p>21 presented in terms of months. It's 30-day</p> <p>22 supply, 60-day supply, 90-day supply. I</p> <p>23 guess you would convert your days to months</p> <p>24 in the data to make it easy so that it</p> <p>25 corresponded very cleanly with this. But</p>

<p style="text-align: right;">Page 342</p> <p>1 L. Craft</p> <p>2 that's actually not a particularly hard</p> <p>3 statistical programming exercise to do, the</p> <p>4 counting. That's all the software is doing</p> <p>5 is it is counting the number of monthly</p> <p>6 observations for each of those product</p> <p>7 categories.</p> <p>8 Q. Okay. If it -- this</p> <p>9 calculation were -- strike that.</p> <p>10 So in this case, despite having</p> <p>11 the necessary data points to construct the</p> <p>12 consumption record, you did not perform any</p> <p>13 of that analysis to demonstrate that this</p> <p>14 methodology could be programmatically</p> <p>15 applied to determine which individuals</p> <p>16 actually meet the threshold for inclusion in</p> <p>17 the medical monitoring class, right?</p> <p>18 MR. STANOCH: Objection to</p> <p>19 form.</p> <p>20 Asked and answered.</p> <p>21 Go ahead.</p> <p>22 A. I only had the unique</p> <p>23 identifiers within each retailer because all</p> <p>24 of the other identifying information that</p> <p>25 consumers was withheld was not produced. I</p>	<p style="text-align: right;">Page 344</p> <p>1 L. Craft</p> <p>2 record linked to unique member IDs within</p> <p>3 each of the pharmacy chain defendants. I</p> <p>4 did not have any ability to crosswalk a</p> <p>5 single individual across pharmacies because</p> <p>6 none of the other personally identifying</p> <p>7 information has yet been seen.</p> <p>8 Q. Okay.</p> <p>9 In this case, we talked about</p> <p>10 the recall of valsartan that occurred in</p> <p>11 July of 2018 through March of 2019 briefly.</p> <p>12 So my question is are you aware of what the</p> <p>13 practice -- actually, strike that.</p> <p>14 Another hypothetical I wanted</p> <p>15 to ask you about, if the threshold fill for</p> <p>16 inclusion in the medical monitoring class</p> <p>17 based on plaintiffs' criteria for LCT was</p> <p>18 the refill that occurred just prior to the</p> <p>19 recall, then that class member filled a</p> <p>20 replacement medication five days after its</p> <p>21 valsartan recall, how would you account for</p> <p>22 that in your consumption record?</p> <p>23 MR. STANOCH: Objection.</p> <p>24 Excuse me. I'm sorry,</p> <p>25 Ms. Anders.</p>
<p style="text-align: right;">Page 343</p> <p>1 L. Craft</p> <p>2 was not able to match records for consumers</p> <p>3 across pharmacies. So I couldn't -- I could</p> <p>4 have -- I could have performed that</p> <p>5 exercise, but it would have been a gross</p> <p>6 understatement because it wouldn't have</p> <p>7 included prescriptions that were filled by</p> <p>8 the same individual of these challenged</p> <p>9 products that were sold at different</p> <p>10 pharmacy chains and I didn't have the PBM</p> <p>11 data that would be an alternative data</p> <p>12 source for performing this exercise.</p> <p>13 Q. I thought you said earlier you</p> <p>14 did have the necessary information to</p> <p>15 perform the construction of a consumption</p> <p>16 record.</p> <p>17 Did I misunderstand your</p> <p>18 earlier testimony?</p> <p>19 MR. STANOCH: Objection to</p> <p>20 form.</p> <p>21 Misstates prior testimony.</p> <p>22 Asked and answered.</p> <p>23 A. Or I misunderstand your</p> <p>24 question. That's a possibility as well.</p> <p>25 What I had was consumption</p>	<p style="text-align: right;">Page 345</p> <p>1 L. Craft</p> <p>2 Objection to form.</p> <p>3 Incomplete hypothetical.</p> <p>4 Lacks foundation.</p> <p>5 Ambiguous.</p> <p>6 Compound.</p> <p>7 Ms. Craft, if you can follow it</p> <p>8 the best, you can try to answer.</p> <p>9 A. I think I get the point, which</p> <p>10 is that you are suggesting that the consumer</p> <p>11 threw away all or part of that last</p> <p>12 prescription and didn't consume it.</p> <p>13 Q. Correct.</p> <p>14 A. Well, you've changed the</p> <p>15 assumption. As I told you earlier in my</p> <p>16 testimony today, I am using purchase as a</p> <p>17 proxy for consumption, which is what's done</p> <p>18 in the peer-reviewed scientific literature</p> <p>19 is using the purchase as a proxy for</p> <p>20 consumption.</p> <p>21 If for some reason you decided</p> <p>22 it was necessary to make a contrary</p> <p>23 assumption and say gosh, we're going to say</p> <p>24 that consumers stop taking the drug after it</p> <p>25 was recalled, of course that's contrary to</p>

<p style="text-align: right;">Page 346</p> <p>1 L. Craft</p> <p>2 the recommendation that was issued, which is</p> <p>3 repeatedly cited by Mr. Kosty, that take it</p> <p>4 until you can get a replacement.</p> <p>5 Yeah, I had not anticipated</p> <p>6 looking to see when the consumer next filled</p> <p>7 another anti-hypertensive. I suppose one</p> <p>8 could, but I had not planned to do that and</p> <p>9 the data that has been supplied thus far</p> <p>10 doesn't necessarily include all other</p> <p>11 products that could be prescribed to treat</p> <p>12 similar underlying conditions.</p> <p>13 Q. Well, it's not really a</p> <p>14 changing the assumption that everything</p> <p>15 dispensed was consumed if we have pharmacy</p> <p>16 data that shows what the replacement</p> <p>17 medication -- when it was actually filled,</p> <p>18 right?</p> <p>19 MR. STANOCH: Objection to</p> <p>20 form.</p> <p>21 Incomplete hypothetical.</p> <p>22 Assuming facts that such was in</p> <p>23 that data.</p> <p>24 Ambiguous.</p> <p>25 Go ahead.</p>	<p style="text-align: right;">Page 348</p> <p>1 L. Craft</p> <p>2 I don't know that that's the</p> <p>3 right thing to do from a clinical point of</p> <p>4 view, but from a data point of view, it's</p> <p>5 not materially harder to add a limiting</p> <p>6 factor that says but take the last</p> <p>7 prescription and then if there's anything</p> <p>8 that should have been still in the</p> <p>9 consumer's possession on the recall date,</p> <p>10 deduct that from the consumption record.</p> <p>11 Q. Do you acknowledge that you</p> <p>12 have not accounted for situations where the</p> <p>13 dispense record for recalled valsartan</p> <p>14 should not, based on other available data of</p> <p>15 replacement medications, it should not be</p> <p>16 assumed that the valsartan was actually</p> <p>17 consumed?</p> <p>18 MR. STANOCH: Objection to</p> <p>19 form.</p> <p>20 Misstates testimony.</p> <p>21 A. I'm not suggesting that you</p> <p>22 should use a record of replacement. I think</p> <p>23 that adds a level of complication that's</p> <p>24 inappropriate to the analysis. I do think</p> <p>25 that in addition to just having -- in the</p>
<p style="text-align: right;">Page 347</p> <p>1 L. Craft</p> <p>2 A. You're also assuming that when</p> <p>3 you see another product prescribed that it</p> <p>4 is prescribed as a replacement.</p> <p>5 So my methodology as proposed</p> <p>6 is to create a consumption record for the</p> <p>7 challenged VCDs and to treat them as all</p> <p>8 having been consumed. If you decided that</p> <p>9 for some reason you wanted to clip off the</p> <p>10 portions that were -- would have been not</p> <p>11 yet consumed on the data of recall because</p> <p>12 it was a recent fill, you could certainly do</p> <p>13 that. The very same procedure that I</p> <p>14 described a moment ago where I said you're</p> <p>15 going to schedule all of the -- for each</p> <p>16 consumer, we've got all of their linked</p> <p>17 purchases, you could say don't count any</p> <p>18 purchase of, you know, a recalled Aurobindo</p> <p>19 product after the date of its recall. You</p> <p>20 could say that. Or you could say if it's a</p> <p>21 30-day fill, assume they didn't take the</p> <p>22 days that overlap, that would have been</p> <p>23 remaining in the bottle after the recall</p> <p>24 occurred. You could make it more</p> <p>25 conservative by trimming those off.</p>	<p style="text-align: right;">Page 349</p> <p>1 L. Craft</p> <p>2 claims processing aspect of the case at the</p> <p>3 end having consumers who seek to participate</p> <p>4 in the medical monitoring class verify</p> <p>5 whether they consumed all the medication</p> <p>6 they bought is step one and very easy.</p> <p>7 If you wanted a more</p> <p>8 conservative analysis that says I'm going to</p> <p>9 assume that any drug that would have been on</p> <p>10 hand after the recall they didn't consume,</p> <p>11 you could make that assumption and come up</p> <p>12 with a more narrowly tailored set of medical</p> <p>13 monitoring class members. It would not be</p> <p>14 materially harder to do that. You would</p> <p>15 just be adding one more limiting factor to</p> <p>16 the aggregate quantities for each consumer.</p> <p>17 So I don't see any scenario in</p> <p>18 which one needs to look too the date of</p> <p>19 prescription and fill of a potential</p> <p>20 replacement drug.</p> <p>21 MR. STANOCH: With that</p> <p>22 counsel, I understand that we've hit</p> <p>23 the seven-hour mark, so I believe the</p> <p>24 defense questioning is over now.</p> <p>25 MS. ANDRAS: I haven't</p>

<p style="text-align: right;">Page 350</p> <p>1 L. Craft</p> <p>2 concluded my questions. I didn't</p> <p>3 realize we were up against the time</p> <p>4 limit.</p> <p>5 MR. STANOCH: Maybe we'll take</p> <p>6 a break and we'll assess if we have any</p> <p>7 questions at all and we're done.</p> <p>8 MR. DORNER: Dave, just before</p> <p>9 you go, don't forget that you had asked</p> <p>10 to make sure that our exhibit letters</p> <p>11 and numbers were harmonized. So if</p> <p>12 y'all are going to go off, I ask that</p> <p>13 you at least stick around so we can</p> <p>14 take care of that.</p> <p>15 MR. STANOCH: If you're okay,</p> <p>16 Drew and Tiffany, we'll go off the</p> <p>17 record.</p> <p>18 Is that good?</p> <p>19 MR. DORNER: Yes. Sure.</p> <p>20 THE VIDEOGRAPHER: The time is</p> <p>21 4:38.</p> <p>22 We're going off the record.</p> <p>23 (Recess taken)</p> <p>24 THE VIDEOGRAPHER: The time is</p> <p>25 4:43.</p>	<p style="text-align: right;">Page 352</p> <p>1</p> <p>2 CERTIFICATION</p> <p>3 I, SARA K. KILLIAN, RPR, CCR, do</p> <p>4 hereby certify that LAURA CRAFT,</p> <p>5 the witness whose examination under oath</p> <p>6 is hereinbefore set forth, was duly sworn,</p> <p>7 and that such deposition is a true record</p> <p>8 of the testimony given by such witness.</p> <p>9 I FURTHER CERTIFY that I am not</p> <p>10 related to any of the parties to this</p> <p>11 action by blood or marriage, and that</p> <p>12 I am in no way interested in the</p> <p>13 outcome of this matter.</p> <p>14 IN WITNESS WHEREOF, I have hereunto</p> <p>15 set my hand this 18th day of January, 2022.</p> <p>16</p> <p>17 </p> <p>18 SARA K. KILLIAN, RPR, CCR</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 351</p> <p>1 L. Craft</p> <p>2 We're back on the record.</p> <p>3 MR. STANOCH: This is David</p> <p>4 Stanoch, counsel for plaintiff and the</p> <p>5 witness.</p> <p>6 We have no questions. This</p> <p>7 deposition is concluded. We'll read</p> <p>8 and sign.</p> <p>9 THE VIDEOGRAPHER: The time is</p> <p>10 4:44. This ends today's deposition.</p> <p>11 (Time noted: 4:44 p.m.)</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 353</p> <p>1 DAVID STANOCH, ESQ.</p> <p>2 d.stanoch@kanner-law.com</p> <p>3 February 28, 2022</p> <p>4 RE: In Re: Valsartan, Losartan, Et Al v.</p> <p>5 2/18/2022, Laura Craft (#5092466)</p> <p>6 The above-referenced transcript is available for</p> <p>7 review.</p> <p>8 Within the applicable timeframe, the witness should</p> <p>9 read the testimony to verify its accuracy. If there are</p> <p>10 any changes, the witness should note those with the</p> <p>11 reason, on the attached Errata Sheet.</p> <p>12 The witness should sign the Acknowledgment of</p> <p>13 Deponent and Errata and return to the deposing attorney.</p> <p>14 Copies should be sent to all counsel, and to Veritext at</p> <p>15 errata-tx@veritext.com.</p> <p>16</p> <p>17 Return completed errata within 30 days from</p> <p>18 receipt of testimony.</p> <p>19 If the witness fails to do so within the time</p> <p>20 allotted, the transcript may be used as if signed.</p> <p>21</p> <p>22 Yours,</p> <p>23 Veritext Legal Solutions</p> <p>24</p> <p>25</p>

<p style="text-align: right;">Page 354</p> <p>1 In Re: Valsartan, Losartan, Et Al v. 2 Laura Craft (#5092466) 3 ERRATA SHEET 4 PAGE____ LINE____ CHANGE____ 5 _____ 6 REASON_____ 7 PAGE____ LINE____ CHANGE____ 8 _____ 9 REASON_____ 10 PAGE____ LINE____ CHANGE____ 11 _____ 12 REASON_____ 13 PAGE____ LINE____ CHANGE____ 14 _____ 15 REASON_____ 16 PAGE____ LINE____ CHANGE____ 17 _____ 18 REASON_____ 19 PAGE____ LINE____ CHANGE____ 20 _____ 21 REASON_____ 22 _____ 23 _____ 24 Laura Craft Date 25</p>	<p style="text-align: right;">Page 355</p> <p>1 In Re: Valsartan, Losartan, Et Al v. 2 Laura Craft (#5092466) 3 ACKNOWLEDGEMENT OF DEPONENT 4 I, Laura Craft, do hereby declare that I 5 have read the foregoing transcript, I have made any 6 corrections, additions, or changes I deemed necessary as 7 noted above to be appended hereto, and that the same is 8 a true, correct and complete transcript of the testimony 9 given by me. 10 _____ 11 _____ 12 Laura Craft Date 13 *If notary is required 14 SUBSCRIBED AND SWORN TO BEFORE ME THIS 15 _____ DAY OF _____, 20____. 16 _____ 17 _____ 18 _____ 19 NOTARY PUBLIC 20 _____ 21 _____ 22 _____ 23 _____ 24 _____ 25</p>
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[& - 428]

Page 1

&	15 26:22 105:3 136:11 261:9	2016 160:18 331:5	353:17
& 2:4,14 4:12,19 5:4,12,20 6:4,12 6:20	150 207:24 208:9 15219 4:15 5:16 16 29:3 133:22 261:6	2017 160:18 191:24 2018 157:9 160:8 160:11,19 167:22 191:24 331:6 344:11	300 3:9 5:6 301 5:14 30s 159:20 31 102:3,8,12 103:4 163:18,21
0	160 103:13 339:20 164 102:25 17 156:25 1700 5:6	2019 69:11 185:17 344:11 2021 38:24 102:4,8 102:12 103:4 105:19	32 8:13 166:8 205:16 330:16,17 320 338:7,13,15,17 341:17
02109 6:23 07102 4:7 08540 7:14	18 1:10 9:3 156:25 331:6 338:9,18 1875 3:9 18th 352:15 19 163:19 19106 2:17 1980 10:18 1:45 232:18	2022 1:10 9:4 102:2 352:15 353:3 21 7:13 8:12 183:8 22 184:2 2200 4:21 23 101:22,24 232 8:22 2525 7:6 27 133:21 135:21 135:23 136:17 195:2 271,163.75 103:24 27th 6:22 28 353:3 2800 6:6 2875 1:4 29 157:5 177:4,6 2nd 3:22	322 8:6 32nd 4:14 33 183:9,24 33131 3:23 33134 7:7 333 3:22 33431 3:10 34 183:25 220:3 3600 4:21 37 8:15 38th 5:14 39 241:13 3:10 295:14 3:24 295:18 3:58 322:10
1	2	3	4
1 8:10 13:25 14:19 14:22 37:17 102:2 102:7 161:13 302:2,7 10,000 302:9 100 127:3 289:2 302:23 314:22 1000 7:6 10019 6:15 101 8:18 1037 4:6 10:13 109:5 10:19 109:3 10:23 109:10 10th 16:8 11 5:22 50:17 11,586 41:2 11,600 252:6 11:55 182:23 12 26:17,22 123:25 124:5 127:17 289:12,14,20 290:15 303:23 12,000 41:3 303:7 12316 26:20 12:12 61:25 12:33 183:4 12:35 232:13 13 161:3,7 14 8:10 161:3,8	2 8:12 21:20,21 26:15 30:25 31:2 31:23 32:3 34:24 37:17 158:8,20 2,500 16:25 2,949 41:4 2/18/2022 353:5 20 116:9 127:18,22 150:20 151:4 177:3 182:10,12 182:15 355:15 20006 5:7 201 8:19 2010 244:6,8 2012 160:22 161:3 161:7 184:18 225:21 2013 184:6,19,23 185:17 2014 331:4 2015 157:8 160:8 160:14,18	3 8:13 32:11,15 33:9 36:22 37:17 294:16 3,000 17:2 41:6 57:9 252:5,12 30 47:25 159:18 177:5,6 179:8 213:8 330:24 341:21 347:21	4 8:15 36:24 37:2 37:17 42:22 52:21 62:14,17 84:17 109:16 183:7 220:4 240:8 258:5 258:18 295:25 335:23 40 241:13 245:22 335:15 41 258:5,18 426 40:9 42:14 4268 352:18 428 45:16,24 46:12 46:15,22

[43 - accurate]

Page 2

43 195:3 271:2 4400 3:22 443 295:3 45 196:14,16 316:6 45202 6:7 46204 5:23 467 247:17 248:2 47 8:16 4:06 322:14 4:38 350:21 4:43 350:25 4:44 351:10,11	62 258:4,18 64 260:6,16 330:15 330:18,23 65 270:24 271:5 272:4 273:19 278:16 281:23 66 280:14,19 284:3 68 295:2 296:2 298:2 299:23 313:13 316:6 69 329:24 330:2 6th 4:6	96 69:12 98 69:12 166:12,15 166:19 167:12,17 167:20 9:07 62:5 9:14 62:10 9th 6:14 105:19	accessed 35:25 72:3 138:6 accessible 14:5 34:15 accommodate 151:20 232:5 accompany 185:9 account 42:8 72:20 81:13,17 114:21 122:17 133:6 139:9,10,15 139:15 143:18 146:16,18 158:7 167:25 169:23 194:17 226:4 257:12 267:7 269:7,8 272:18 274:7,18 278:18 282:7,19 293:10 293:15,21 296:21 296:23 297:9 298:15 299:24 300:14 301:15 308:20 325:23 344:21 accounted 163:24 348:12 accounting 118:7 125:24 311:5 accounts 71:23 97:7 166:2 270:16 274:11 290:10 accumulated 179:16 accuracy 26:4 213:18 353:9 accurate 17:10 29:18 32:5 51:9 56:10 58:11 65:6 72:4 73:2 74:14 82:3 85:14 86:5
5	7	a	
5 8:16 47:10,11 48:21 50 202:8 260:2,3 298:8 340:14 500 2:16 5092466 353:5 354:2 355:2 51 6:14 205:16,18 215:12 245:22 510 2:16 52nd 6:14 53 6:22 54 220:3 338:9,19 550 100:24 101:6 5500 177:9,12,17 177:21 178:8,22 58 48:21 49:14 59 48:22 49:18 296:3	7 8:19 201:20,22 202:8,24 329:20 329:25 701 2:6 70310 2:7 72 163:24 166:2 75201 4:22 770 247:11	a.m. 1:10 abbreviates 170:12 abbreviation 105:11 abc 223:21 ability 16:13 25:17 76:23 94:24 277:9 290:5 307:2 344:4 able 14:11 22:4 28:20 31:17 71:22 83:17 96:21 100:8 116:14 135:11 137:17 141:13 143:18 147:18 191:10 219:20 231:21 254:14 267:2 269:18 270:21 278:23,25 337:2 343:2 absence 111:13 absolutely 42:13 87:20 132:25,25 144:20 212:10 259:6 307:7 328:5 absorbed 161:24 abundance 40:14 academic 215:3 acceptable 182:11 accepting 65:24 access 37:15 85:23 181:4,11	
6	8		
6 8:18 101:7,12 105:3 161:13 60 201:21 202:24 240:8 243:15 341:22 600 6:6	8 8:22 105:25 232:21 233:2 235:25 236:2 238:13 240:6 247:7 248:2,8 258:10,13 80 335:18 88 89:21 288:4,5 289:8 89 240:8 8:00 1:10 8:09 9:3		
	9		
	9 8:5 106:3,18,23 106:25 90 159:19,19 341:22		

[accurate - agree]

Page 3

87:2 93:10,20 102:22 103:17 136:24 164:9 215:13 233:7 271:17 272:17 282:21 326:15 accurately 66:19 103:11 accusing 106:14 achieve 67:20 achieved 176:15 acknowledge 348:11 acknowledgement 355:3 acknowledgment 353:12 acquired 157:10 161:23 162:10 163:12 191:25 acquirer 161:13 acquiring 162:8 162:11 acquisition 161:17 acquisitions 162:5 act 55:19 183:13 acting 71:2 128:22 133:10 134:18,18 288:19 309:3 313:23 action 252:24 319:10 352:11 actions 130:2 220:7 active 11:18 52:11 52:13 activity 33:5 263:6 acts 162:6 192:2,3 actual 36:5 107:15 149:9 165:14 211:22 216:20	263:14 307:4 313:8,16,24 314:2 actuarial 241:17 241:19,23 add 29:14,15 103:15 125:19 220:18 246:15 341:8,8 348:5 added 29:22 103:23 209:2 336:21 341:13 adding 341:10 349:15 addition 20:23,25 348:25 additional 41:8 51:7,13 65:4 92:23 102:5 126:14 133:25 135:22 136:16 271:3 272:12 273:25 275:18 276:18 278:15,17 281:22 282:18 283:21 296:9 309:9 additions 355:6 address 35:22 54:3 69:25 70:16 94:24 99:6 209:19 216:13 addressed 87:14 92:24 145:23 addresses 33:22 36:6,15 70:10 94:22 202:21 214:23 adds 348:23 adduced 59:3 adequacy 33:19 99:13 279:24	adequately 99:6 adherence 214:24 adjective 241:23 adjudicate 269:18 adjudicated 223:22 adjudication 69:24 129:6,24 131:25 132:12 141:11,12 142:2 142:23 143:16 144:19 145:24 158:25 260:19 273:2,3,20 282:5 309:25 310:6 adjusted 44:15 adjustment 160:14 adjustments 114:21 115:6,19 117:25 118:7 administered 137:21 administration 180:4 administrative 76:12 83:10 129:18 290:4 administrator 131:19 132:9 134:11 148:22 181:9,11 286:8 291:21 300:22 307:23 310:25 311:21 317:20 administrators 25:25 79:12 129:19 155:5 178:6,11 179:3,17 180:2	admittedly 85:21 adopted 277:14 advance 122:3 adversely 60:21 advise 131:21 312:8 advisor 311:22 312:6,21 aetna 303:10,11 affect 16:12 24:15 47:4 213:18 affiliate 221:5,6,6 affiliated 220:10 220:22 221:21 223:8,10 229:22 288:16 affiliates 222:2 258:12 agency 243:17 244:2 aggregate 123:11 125:25 126:2 349:16 aggregated 125:16 aggregation 126:5 302:20 aging 190:22 ago 23:7 45:20 46:11 52:17 137:25 168:3 258:8 271:11 301:11 347:14 agree 12:10,24 17:17 44:7 89:18 97:25 109:21 112:17 117:22 129:12 137:7 152:6,25 153:7,8,9 177:21 183:14 188:9 203:5,8,13 209:24 210:12
--	--	--	---

[agree - andras]

Page 4

326:6 331:14 332:9,14 agreeable 271:15 agreeing 151:17 153:5 agreement 125:5,8 309:25 agreements 189:12,16 ahead 13:22 15:20 22:11 24:8 26:12 33:15 36:22 38:20 41:19 43:9,17 44:13 45:8 46:19 47:7 49:10 52:19 52:20 54:20 56:18 58:15 59:18 64:7 68:23 73:16 74:23 77:19 79:19 82:11 82:23 84:12 85:9 88:24 91:12 92:10 92:22 93:17 101:11 103:8 106:17 108:15 110:4 111:10 115:4 119:2,10 120:16 121:22 123:3 127:16 129:9 132:24 137:5 141:4 162:19 164:25 180:22 187:20 188:4 192:23 198:2 201:7,20 203:10,22 205:10 210:11 211:8 214:3 215:21 218:10 220:2 222:6 225:12 226:13 228:25 232:24 237:16	241:8,21 245:21 251:12 256:8 260:5 262:9 267:12 276:24 278:9 282:25 285:5 291:7 292:13 301:3 302:18 306:12 309:16 311:14 313:20 318:18 320:15 323:6 324:14 325:15 326:5 327:10 328:16 329:11 333:6 336:7 338:3 340:25 342:21 346:25 aid 5:21 al 353:4 354:1 355:1 albertson 5:5 alek 3:15 alfano 5:12 algorithm 176:13 allegation 92:4 allegations 45:5 91:15 93:2 210:22 allege 43:21 46:2 alleged 318:13 allegedly 209:9 allocation 75:24 149:7 264:15 allotted 353:20 allow 176:17 269:5 315:6,15 allowed 10:6 94:9 181:13 allows 50:8 84:5 139:6 253:10 277:15	alongside 296:13 299:3 alpha 13:24 261:18 262:15 266:7 alternative 71:9 219:4 325:18,23 343:11 alternatives 337:4 ambiguity 294:24 303:19,20,25 304:4 ambiguous 64:5 68:20 74:21 79:16 82:7 88:22 92:9 93:14 115:3 118:25 120:14 121:20 122:25 125:2 132:23 141:2 157:24 162:18 169:18 172:16 175:16 207:3 212:6 213:25 226:11 308:9 311:12 325:12 326:25 327:9 338:2 340:23 345:5 346:24 amenable 27:21 41:16 amended 8:10 american 291:12 291:14 amerisource 203:17 amerisourceberg... 6:5 amlodipine 44:10 44:10	amount 34:11 120:19 157:19 161:22 175:2 201:12 209:24 211:18 212:18 218:4 227:8 283:17,20 325:7 amounts 114:18 114:20 213:17 242:2 314:5 323:22 325:25 335:10 analogous 219:8 311:17 analysis 24:6 29:20 30:3,5 32:21 42:19 46:12 47:3 48:11 49:15 49:19 157:15 237:8,10 241:17 241:19 245:14 251:24 278:5 325:22 327:6 332:20 340:12 342:13 348:24 349:8 analyst 337:16 analytic 27:23 analytical 27:17 analytics 8:18 101:5 327:4 analyze 60:2 193:18 218:25 299:17 analyzed 214:9 218:17 anders 344:25 andras 3:24 8:6 321:25 322:17,19 326:7 327:2 329:14,23 330:3
--	---	--	--

[andras - ascertainability]

Page 5

349:25 annotations 16:4 annual 158:9 159:10 245:17 anonymize 35:16 anonymized 35:10 35:12 36:2 answer 12:8 18:2 19:13 28:17 38:24 41:20 48:18 51:23 66:3 73:11 87:8 95:6 98:11 104:16 106:15 110:24 114:5 122:14 147:17 149:11 150:11 167:8 168:18 169:4 175:2,17,24 199:6 199:25 200:10,18 200:20 201:5,8,15 201:16 207:19 211:8 212:8 214:5 218:10 226:14 228:24 231:7,19 269:4,22,24 270:4 287:2 288:4 302:18 307:10 321:11 325:17 345:8 answered 56:16 79:17 98:5 115:24 122:22 123:22 144:6 150:7 174:10 175:14,20 180:20 193:8 194:14 199:3,12 200:25 213:22 251:4,11 254:22 276:23 285:2 286:24 291:4 292:9 298:13	299:7 308:6 318:16 328:15 342:20 343:22 answering 66:5 answers 240:21 anti 256:25 346:7 anticipate 178:23 anticipated 346:5 antitrust 86:15 91:14,24 92:3,11 170:3 218:12 219:11,15 227:23 319:5,22 anybody 12:16 13:15 14:6 16:16 35:2 121:12 145:16 152:7 305:10 anyway 340:6 api 40:19 52:18 183:15 204:16 329:5 336:17,18 338:9,9,10,17,19 338:20 339:2,12 339:15 341:8,10 341:14,17,18 apologize 106:12 112:8 127:19 147:13 150:23 337:2 apparent 80:23 307:15 appear 28:7 33:18 40:11 103:24 120:25 134:2 149:11 284:21 285:11 286:19 288:12 290:24 293:9,10,12,13 300:7,10,19,20 302:8	appeared 33:3 233:25 appearing 301:20 appears 102:21 105:18 127:23 280:22 284:5 290:18 296:12 300:13 301:14 309:9 append 336:18 appended 339:2 355:7 applicable 353:8 application 50:12 50:21 56:2 123:19 applied 41:22 42:14 50:10 53:7 148:3 213:6 251:6 268:6,20 320:8 325:6 342:15 apply 25:15 160:2 231:20 233:23 249:4 250:24 258:9,16 338:5,11 applying 120:7 259:8,16 appreciate 21:11 26:10 41:11 56:6 58:6 68:5 73:3 77:5 101:9 108:22 149:19 152:11,12 182:5 196:9 213:12 219:25 249:23 260:15 295:21 318:2 approaching 116:8 appropriate 42:11 152:16 236:14 260:19 272:15 323:17	appropriations 244:20 approvals 44:3 approved 237:22 approves 52:17 approximate 299:2 approximately 102:25 163:24 approximation 168:2 arbitrarily 61:15 archival 163:7 area 215:3 216:6 areas 107:8 argumentative 141:4 arises 181:7 306:4 arrangement 168:17 191:18 218:9 305:17 310:23 arrangements 191:21 241:8 313:15 array 132:6 arrive 277:6 arrived 102:24 208:10 arrives 192:7 article 162:3 216:16 234:14 ascertain 57:4 251:18 ascertainability 54:6 55:9,10 56:11,21,25 57:11 58:8,19,23 59:2,6 59:8 65:12 66:2 85:6 131:24 172:19,21 237:24
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[ascertainability - attention]

Page 6

322:25 323:8,13 323:14 324:21 ascertaining 204:19 209:16 asked 53:5 54:3 56:16 60:19 79:17 82:13 98:5 115:24 121:5 122:22 123:21 144:6 150:7 168:3 175:14 180:13,20 185:15 193:18 194:14 199:3,12 199:19 200:17,25 212:20 213:22 214:5 221:19 228:24 229:11 249:3 251:4,11 254:22 276:23 285:2 286:24 291:4 292:9 298:13 299:7 301:22 308:6 317:25 318:16 319:17 324:4 326:8 328:15 342:20 343:22 350:9 asking 11:25 74:12 77:8 78:22 119:3 121:23 130:21 152:13 155:15 171:5 194:10 211:11 212:17 278:24 300:4 321:8 337:6 337:10 asks 65:22 218:14 283:17 aso 70:25 72:22 74:11 75:13 76:7	76:14 79:11 80:10 80:21 81:23 82:2 82:17 83:16,21,24 91:4 96:14,24,25 96:25 97:9 99:8 128:18 129:17,23 130:2,4,12,13,18 130:19 132:15,17 132:18 134:10,18 137:22 146:25 147:22 148:10,12 148:16,25 149:4,5 149:10,16 150:2 150:17 261:3 266:23 267:3,7,15 269:7 273:15 284:23 285:8 286:7,12,17 287:9 287:22 288:19 289:17,25 290:21 291:21 293:18 294:6 296:13,19 296:24 297:16,24 298:10,16,18 299:4,24 300:5,6 300:21 301:13 302:7 304:6,15 305:17,19,24 306:10 307:5,13 307:15,23,25 308:2,13,14,18 309:3,7,8,17,18 310:5,6,18 312:9 312:11 313:10 314:19 315:6,16 316:9,14 317:3,6 317:16 aso's 290:24 315:9 315:19 asos 25:25 71:17 71:18 86:22 94:25	132:8 155:4 171:11,14 304:8 aspect 250:3 349:2 aspects 61:9 84:13 324:13 assemble 307:4 321:23 assembling 85:19 assert 76:14 assess 214:14 350:6 asset 161:16 assigned 38:9 262:23 assignees 223:8,11 assigning 127:6 assignments 220:11 221:20 222:3 assigns 262:22 286:8 assistance 255:20 255:21,24 associated 49:6 70:12 71:24 172:21 213:7 222:13 228:4 229:3 233:5 246:25 252:5 261:24 263:7,8,14 266:4 272:20 320:4 association 122:19 assume 12:8 20:12 21:13 78:25 210:24 211:11,16 212:20 216:14 235:21 309:24 347:21 349:9 assumed 348:16	assumes 195:15 201:2 assuming 46:12 59:20 60:3,10,12 66:6 72:11 252:11 286:17 346:22 347:2 assumption 211:11 215:8,24 216:8 224:2 345:15,23 346:14 349:11 assumptions 60:15 assure 31:17 160:19 170:20 atlas 240:14 257:21 attach 39:4 186:11 268:16 attached 47:18 179:12 353:11 attaches 262:24 attachment 42:7 attachments 40:11 attempt 17:25 21:25 94:12 111:12 112:2 168:18 176:7 233:23 249:2,20 250:24 251:7,9 252:16 279:17 312:4 attempted 21:8 57:3 60:2 194:6 214:14 249:9 299:13 attempting 33:17 88:9 161:19 237:19 251:21 attention 44:17 52:23 55:5 57:14
---	---	--	--

[attention - believe]

Page 7

106:9 114:10 attest 217:3 attorney 11:15 104:22 353:13 attorneys 2:5,15 3:5,21 4:5,13,20 5:5,13,21 6:5,13 6:21 7:5 attribute 149:2 attributes 253:11 auditable 305:15 audited 304:25 auditing 132:4 augmented 169:7 178:10 aurobindo 4:13 47:24 335:20 338:10,20 339:15 347:18 authoritative 241:15 authority 250:8 257:24 automated 141:7 142:18 automatic 145:15 147:9 automatically 71:22 134:2 138:12 139:22 140:3,9,15,17 141:24 149:15 190:17 270:22 306:2,14 333:21 availability 253:8 available 62:25 63:14,22 64:23 65:2,7 92:16 121:3 126:15 160:12,17 165:4 218:16 238:2,10	244:8 325:9 348:14 353:6 avenue 3:22 4:21 averages 167:13 212:15 avoid 68:2 93:21 aware 24:4 91:9 111:25 123:13 160:21 193:4 198:3 344:12 axiomatic 113:8 b b 8:8 21:19 37:17 47:18 337:9 339:17 b's 279:21 back 21:25 22:2,5 27:7,11,16 28:8 29:11,16 35:16 40:15 43:18 52:11 52:21 55:2 61:7 62:12,13 66:13 73:23 81:12 90:5 95:8 97:15 101:20 109:2,12,13 113:15,16 116:18 117:17 121:11 130:9 139:24 142:11 149:20 155:10 160:22 170:21 177:3 182:12 183:6 185:14 193:3 194:10 206:9 215:11 227:14 232:20 236:15 240:7 242:15 244:6,8,25 247:20 258:17 261:6 263:2,5 264:16 265:5 266:21	270:5 280:11 283:18 286:14 295:20 302:3 307:9 313:12 314:7 320:9 322:8 322:15 351:2 backbone 141:9 141:10 backward 224:14 backwards 336:20 bad 37:25 102:22 balance 127:6,6 296:18 bare 224:6 barnes 5:20 base 61:7 based 83:21 98:16 98:18 102:22 104:7 116:11 158:4 167:19 169:6 173:3 176:13 178:21 198:16 204:16 208:22 212:15 239:6 268:5 302:10 304:2 318:12 328:10 329:4 339:11,12 341:13 344:17 348:14 bases 63:24 basic 20:9 24:23 34:6 64:9 155:22 156:11 304:14 basically 27:2 95:12 166:9 170:24 261:22 basing 143:25 159:4 basis 99:10 123:11 127:8 158:9	159:10,23 164:20 169:5 235:23 245:17 284:12 324:10 bat 240:13 batch 187:23 188:3,6 batches 113:25 bates 44:15 bazan 3:14 bear 260:10 bearing 288:2 beauty 67:21 beginning 124:8 begins 62:11 109:11 183:5 232:19 295:19 behalf 10:23 71:2 117:6 119:21 130:3 133:10 158:25 316:9 beings 99:20 belabor 11:11 believe 15:3 16:25 19:5 24:9 35:9 36:13 38:21 39:12 46:10 47:3,17 59:4 64:14 66:13 78:24 85:5 86:2 86:19 87:15 88:16 90:25 95:11 97:6 99:4 100:6 112:10 115:5,8,10 117:24 120:5 126:21 130:17 131:12 146:11 152:16 157:8 164:17 168:20 172:3 174:2 184:13 190:5 193:8 199:8 199:23 201:8,17
---	---	--	---

[believe - business]

Page 8

205:11 210:21 220:12 234:16 250:15 290:23 296:2 299:22 301:21 305:9 319:6 326:12 336:15 349:23 belong 179:14 benchmark 55:24 benefit 37:14,20 80:4 81:16 124:6 129:5 131:18 132:9 141:15 239:14 258:22 268:3,5,13,15,19 275:8 289:19 311:21 312:5,21 benefits 72:8 83:3 88:6 89:15,22 98:22,25 130:12 223:14 224:19 231:17 234:11 235:16 238:19 239:2 241:17,19 241:24,25 242:2,3 242:5 243:8,25 244:18 258:25 267:24 287:8 288:8,8,12 289:4 289:14 312:22 bergen 203:18 berman 2:14 berne 6:4 best 38:11 44:19 63:19 178:4 260:9 345:8 bet 28:25 better 18:4 beyond 107:24 210:15 281:12	bid 144:22 244:22 bifurcation 148:19 big 57:11 81:2 159:3,6 173:11 279:12 285:19 291:10 314:17 bigger 161:10 321:8 bill 72:6 83:17,25 137:20 148:25 150:17 270:15 306:2 308:10 314:22 315:7,16 billed 83:11 198:8 286:3 304:18 billing 83:9 97:10 132:3 260:21,25 261:4 270:6,9,18 270:23 273:13 283:5 305:14,16 305:18 307:14,17 308:15 bills 304:17 bily 7:19 9:8 bin 95:13 139:3 146:21 147:19 265:10,11,15,25 266:3,6 271:14 birth 35:23 70:11 176:23 bit 50:2 84:10 95:5 97:16 135:19 168:6 180:23 271:3 280:6 318:4 322:8 330:5 332:7 333:25 bite 303:24 blank 76:17 298:17,17 blind 314:25	blinders 292:15 blood 352:11 blow 177:5 183:25 340:12 blowing 205:17 blue 81:3 263:15 263:18 312:8,10 312:11,15,18 boca 3:10 bockius 4:12 bone 129:3 bones 224:7 books 118:8 borderline 141:3 311:13 borne 198:12 boscik 5:12 boston 6:23 bottle 112:18 113:2,3 347:23 bottles 113:7,9 bottom 112:11 146:14 158:11 bought 122:8 174:22 185:3 191:16 192:19 204:18 215:25 216:11 217:4 289:6 332:2 349:6 boulevard 3:9 4:6 box 264:15 265:5 boxes 265:3 271:24 brand 92:15 218:23 283:14 branding 143:5 brands 219:6 break 61:22 77:10 151:24 153:13 154:15 171:13 182:7,11,18	217:17 232:7,10 267:6 295:23 321:18 333:24 350:6 breaks 12:14 brief 85:17 briefly 100:22 280:18 344:11 bring 21:25 127:25 185:14 194:9 312:9 broad 63:15 64:9 64:19 broadly 168:6 broken 103:13 broker 289:4 311:23,25 312:2,5 312:22 brought 15:2 22:24 112:6 buchanan 5:4 bucket 227:9 building 16:20,22 136:13 built 178:7 bunch 11:11 294:20 312:10 burdensome 198:17 260:4 bureaucracy 245:4 burned 161:15 business 83:22 84:7 99:18 107:6 118:8 135:16 142:14 143:6,11 143:16 145:5 148:12,13 149:18 256:20,24 290:3,9 310:10 312:13,20 314:19,19 316:19
---	---	--	--

[butcher - cash]

Page 9

butcher 84:24	camp 2:6	288:13,25 289:22	210:19 213:6
button 83:17	campbell 5:9	290:19 291:13	217:6,8,24,25
buttons 142:14	canceled 116:9	293:12 300:7	219:15 225:4,17
buy 205:3 288:3	cancellations	309:3	230:14,17 237:4
buying 191:23	117:21	carry 34:9 144:13	238:7 239:18
224:24	cancer 209:18	277:4	240:23 241:18
byproduct 142:7	candor 318:2	case 9:23 10:22	242:10 275:13,19
c	cap 141:20	18:15,20 20:5	279:2 285:23
c 2:2 3:2 4:2 5:2	capability 256:18	23:16 24:12,16	286:11,21 290:23
6:2 7:2 9:17 10:15	capable 17:14	26:5,13 27:3,23	299:15,20 305:17
10:15 32:10 37:17	150:8,13	33:25 37:6 43:5	307:21 318:12
calculate 299:14	capacity 10:22	43:20 48:5 57:7	320:3,18,24
calculated 206:24	80:12 128:22	60:13 61:9 65:4	321:10 322:20,24
calculation 102:20	130:6 312:11	69:21 76:6,25	323:19,24 325:22
166:16,18 255:2	313:24 316:7	77:15 78:10,17	328:2 339:13
342:9	capitation 235:2,4	80:6 81:6 84:25	342:10 344:9
calculations 41:14	captured 113:17	85:5,7,13,23 86:2	349:2
41:15 327:21	card 149:24	86:13,13,19 87:7	cases 51:15,19
calculus 324:23	262:19 263:16	87:10,18 88:4,16	80:18,22 82:17
california 11:16	269:21	90:4,4,9,11,18,23	84:21 92:12 94:12
17:3 248:3	cardholder 139:2	91:13,14,18,24	125:11 146:4
call 12:16 13:16	147:4,21 261:17	92:4,25,25 93:4	148:2 159:17
20:3 39:7 49:23	cardinal 203:17	94:3,8 97:24	170:4 179:4
77:7 112:7 136:10	care 37:18 135:5	98:11 100:3,14	180:17 181:19
220:6 261:3	225:24,25 226:3	102:25 103:19	186:12,16,21
271:12 272:14	227:16 230:2	104:20 107:11,15	191:9,14 192:4
275:25 276:2	234:22,25 235:11	107:15 110:10	218:12 227:23
319:19	235:14,17,20	115:18 118:19	235:9 259:20,22
called 19:17 48:11	236:2 237:7,9	120:20 124:12,22	274:16 277:20
73:10 126:17	238:5 253:15	125:7,8 148:16	279:8 283:11
144:9 176:16	302:22 314:3	160:22 162:11	290:21 293:2
276:6,7 277:23	350:14	165:7,25 166:23	294:8,11 306:6
281:8 293:6,7	career 11:4	167:8,9 168:10,17	308:16,17,25
calling 100:10	careful 28:19	168:21 169:8,11	309:21 316:16
215:14 272:10	75:13 89:2	171:5 172:10	318:22 319:21
calls 58:13 98:7	carried 219:9	178:11,24 180:17	328:2
170:13 300:25	320:6	188:14 191:19	cash 126:10,10,12
calpers 248:2,7,9	carrier 280:22	193:4,24 197:16	158:5,7,11,12,16
248:11,15,20	281:2,6 282:6	198:23 200:12	158:22 222:8
249:14	284:6,22 285:12	201:10 202:25	224:20,24 225:9
	285:25 286:19	206:13,24 207:22	230:2 253:21

[cat - claims]

Page 10

cat 67:2 catamaran 163:10 163:12 catch 44:19 226:20 catching 255:23 categories 64:8,19 220:15 236:8 339:6,7 342:7 categorization 236:5 category 265:21 287:20 caught 203:7 caused 110:15 caution 40:15 87:4 90:15 98:8 167:5 168:14 169:19 171:19 207:4 208:15 218:6 259:10 279:5 319:14 cautioning 241:5 cautious 244:4 ccr 352:3,19 cell 17:15 central 107:16 centre 4:14 5:15 certain 81:16 177:20 315:6,15 certainly 12:20 24:17 26:7 70:15 95:22 123:5 137:12 145:21 165:19,21 170:3 178:3 208:18 219:23 227:22 242:4 244:11 259:4 276:25 292:18 316:24 317:8 321:5	327:25 347:12 certainty 215:15 certification 53:16 58:10 352:2 certified 1:16 certify 352:4,9 chain 55:19,21 183:12,23 216:16 344:3 chains 343:10 challenge 25:17 94:19 challenged 69:9 86:3 88:3 110:10 111:18 324:18 332:2 343:8 347:7 champus 250:9 chance 28:24 chandra 105:12 chang 215:4 change 24:17 27:25 40:16,25 46:25 118:9 163:8 191:18 244:12 245:12 258:6 296:9 354:4,7,10 354:13,16,19 changed 27:20 41:10 107:19 245:20 345:14 changes 28:2,18 29:12,13,17 39:14 39:21 92:12 176:18 353:10 355:6 changing 170:16 346:14 channels 160:6,18 characteristics 113:18	characterization 64:22 74:4,15 87:10 89:18 93:22 137:7 188:10 203:6 233:8 characterizing 82:20 86:25 characters 261:19 262:15 charge 260:22 charles 2:18 check 37:10 41:24 137:17 255:22 256:2 257:21 280:8,8,8,9,9 317:19 321:16 cheekiness 182:5 chemical 61:2 113:13 chip 250:9,13 257:11 choice 285:18 chosen 285:21 christine 4:9 christopher 5:8 chunk 187:17 188:7 cincinnati 6:7 circulation 183:23 circumstances 25:15 123:14 185:12 citations 39:15 cited 18:17 23:9 23:13,14 41:3 69:8 215:4 346:3 cities 242:24 city 249:13 civil 10:7 claim 76:11,15 122:8 123:7 128:8	135:24 136:19 143:25 202:3 204:14 216:3,14 216:19 223:13 225:4 226:22 229:5 230:15 242:6 260:18 265:16,22 269:18 270:23 273:2,3 274:18 278:18 301:17 319:19,20 319:24 321:10 341:5,8 claimants 98:25 268:4 claims 8:14 19:21 32:21 33:6,24 45:12 60:8,20 69:13,19,24,25 70:18,19 72:19 74:5 80:20,24,25 83:6,10,16,18 89:12 96:11,14,15 96:17,22 99:2 100:9 116:7 129:6 129:23 131:25 132:4,12 139:12 140:3,16 141:11 141:12,25 142:8 142:22 144:18 145:24 146:16 149:2,16 150:15 158:25 159:15,22 160:22 166:25 168:9 178:6,11,20 179:3,17 180:2,4 181:9,10 186:14 192:19 195:23 205:11 209:10 214:15,16 217:6,8 220:25 221:8
--	---	--	--

[claims - close]

Page 11

223:20,23 225:2	59:13 60:21 63:6	325:7,25 328:7,10	135:2,7 136:23
225:21 227:25	64:11 65:17 66:15	329:3,22,23	137:19,19 139:8,8
228:2,7,10 229:2	76:23 77:16 82:2	330:12 331:14,22	139:14,15 146:13
229:13 230:13,24	85:12,19 86:23	332:4,10,15 333:3	146:15,18 148:5
234:7 237:21	87:10,24 88:2	335:8 336:2 338:7	150:16,18 163:3,4
243:13,13 254:9	89:5,5,6,9,12,25	342:17 344:16,19	257:12 270:3,10
254:12 256:11	90:10,21 92:19	349:4,13	270:10,16,17
262:25 263:6	109:20 120:9	classes 127:7	272:18 274:7,18
266:4 268:18,20	121:9,13 122:16	205:20 321:6	275:25 278:18
269:6 272:21,23	122:17 123:12	classification	280:22 281:2,4,8
273:10,20 274:17	128:6 155:3	80:20 253:11	282:19 284:6,22
280:21 281:24	164:22 165:13	classifications	285:11,14,19,25
282:3,5,8,12,20	166:12 172:22	254:7,15	286:12,19 287:17
283:2,8,23,24	173:2,20,21,23	classified 339:6,10	288:13,24 289:22
284:5 285:21	174:9,25 175:5,10	339:12	290:19,25 291:13
286:10,17 287:17	176:4 177:23	clean 16:3 173:9	292:4,5,19 293:12
290:18 294:19	178:18,20 179:21	cleanly 341:25	293:21 294:3
296:11 300:18	180:10,17 181:13	clear 35:5 36:3	297:8 300:7,12
301:7 302:8,11,20	181:19,22 188:14	66:9 69:10 73:20	301:14 303:12
303:21,23 306:14	188:18 190:12	75:10 80:14 87:21	308:19 309:2
309:25 310:6	192:13,14 203:14	129:25 131:11	311:4 314:20
312:15 313:10	204:19 207:10	156:18 166:21	client's 275:19
319:21 323:18	209:16 214:17	172:18 173:6	313:15
328:21 335:3	216:21 217:2,3	177:11 198:21	clients 71:16 75:3
340:2,13 349:2	218:4,13,25 219:2	201:13 216:18	83:16,18,25 96:19
clarification 68:5	220:7 226:25	217:21 242:22	97:10 138:6
77:6 101:10	227:21 228:5	246:6 251:15	144:20,22 148:10
127:22 147:2	230:6 231:3	269:23 275:23	148:25 149:16
209:6 219:25	233:16,24 237:22	clearer 97:2	173:6 271:4
231:19 249:24	238:20 239:17,17	clearing 77:9	272:13 274:10
clarified 46:14	240:12 242:19	141:10	285:16,23 289:6
178:9	243:2,9 248:22	clearly 35:21	294:6 301:16,19
clarify 79:20,24	249:4 251:18,20	53:25 65:21	306:3 309:4
95:6 106:7 219:17	251:25 252:23,24	182:18 190:14	312:10 314:23
223:5 247:16	253:3 254:17	237:23 313:3	315:7,9,16,19
320:2	255:4,8,12,14	337:2	316:8,14,17 317:6
clarifying 41:12	259:8,17 276:17	clerk 230:12	clinic 156:20
class 8:19 26:5	276:20 307:3	client 70:24 71:8	clinical 348:3
33:23 40:5 53:6	318:7,11,20 319:4	72:7,13 74:11	clip 347:9
53:15 56:2 57:4,9	319:9,10 320:8,10	80:10 83:9,11,22	close 49:23 52:20
57:19,23 58:10	323:22 324:10,19	104:22 133:6,10	112:7 159:13

[close - concern]

Page 12

160:4 closed 163:4 closely 192:6 cms 240:4 coach 312:22 code 30:4,14,18 40:3,6,22 41:14,22 50:18,18,19 51:16 112:25 267:2 268:22 269:3 340:14 341:15 codes 40:10 45:16 45:18,25 91:21 collapsed 274:17 collect 195:5 196:18 219:21 collected 100:13 100:15 134:4 166:10,23 171:16 196:23 collection 24:24 101:17 132:3 collections 103:23 collective 274:2 collectively 163:23 328:20 colloquy 323:10 337:24 column 48:8 136:12 149:25 202:4,7,23 246:16 247:13 262:14 combination 150:14 261:18 262:15 266:7 267:4 270:20 278:11,15 338:8 combinations 269:5 combine 174:3	combined 209:3 227:3 276:19,25 combining 214:7 come 148:15 159:13 160:3 180:10 193:3 242:15 321:9 337:16 349:11 comes 11:24 12:21 125:4 comfortable 182:7 coming 17:2 22:15 33:11 52:18 84:2 141:23 264:16 294:4 commencing 55:6 commensurate 157:18 comment 107:24 213:9 commercial 170:3 238:22,23,24 244:3 commissioners 72:6 common 59:15 113:14,18 118:14 188:7,12 218:24 220:7 244:14 277:13 296:19 297:15 298:7 commonly 275:24 289:24 296:22 communicate 152:6 327:15 communicating 17:14 communication 97:2 communications 17:19 18:5,8	208:17 comp 100:23 companies 5:5 238:25 281:8 290:8 company 89:10,10 235:19 279:12 285:20 288:3 289:5 290:2 301:13 314:18 317:4,15 company's 224:3 comparatively 158:22 220:23 251:23 compare 165:15 218:22 compared 242:3 comparing 90:3 comparison 158:23 compile 66:14 68:8 175:6 318:23 320:19 compiled 179:4 complaint 210:19 210:22 212:5 complete 22:19 70:17 106:25 133:14 167:10 216:9 223:16 257:17,18 320:20 321:9 355:8 completed 105:20 353:17 completely 80:5 118:4 162:15 293:23 completeness 26:4 279:15,24	complexity 339:10 compliance 135:12 214:24 216:6 compliant 78:21 complicated 51:17 340:6 complication 348:23 complications 170:25 313:9 complied 257:4 components 55:11 55:13 277:21 composition 113:13 compound 56:17 74:22 82:9 118:24 120:15 137:3 157:25 175:15 214:2 217:15 226:12 299:8 302:17 308:8 340:21 345:6 comprehend 16:13 comprehensive 65:23 72:25 127:9 comprehensively 70:23 comprising 99:2 compute 165:19 conceding 66:6 concentrated 167:23 concentration 161:4 211:12 conceptually 188:6 concern 95:8
--	---	--	--

[concerned - consumption]

Page 13

concerned 100:10 131:23 244:17 314:13 concerns 171:7 252:22 concession 340:24 concluded 70:22 93:5 97:23 350:2 351:7 conclusion 47:4 93:9 98:2,7,18 217:6 248:9 conclusions 31:20 98:14 condition 88:2,5 conditions 346:12 conduct 327:5 conference 14:6 14:11 conferring 280:18 confess 76:21 confidential 14:4 80:3 confidentiality 90:17 98:10 167:7 168:16 171:6 218:8 241:7 configuration 173:18 confined 63:25 confirm 24:25 33:19 34:5 41:8 56:8 131:3 258:22 317:9 confirmation 142:3 confirmations 254:12 confirming 67:9 conflate 131:17	conform 60:5 77:24 confused 76:22 179:19 273:6 confusing 99:17 confusion 44:24 277:18,19 280:10 303:17 congratulations 196:6 connect 141:24 188:22 connected 323:14 connection 24:11 37:6 81:25 132:11 239:8 241:9 consecutive 331:10 conservative 167:15 347:25 349:8 consider 59:7 67:5 69:2 78:16 147:5 260:2 337:14 consideration 110:7 considered 131:6 131:8 241:15 considering 136:17 consistency 160:19 consistent 104:2 143:15 144:24 146:8 160:12 173:10 293:23 consistently 302:24 consolidated 67:15 69:3	consolidation 161:5 constant 170:11 construct 205:23 218:3 332:19 335:23 342:11 constructing 328:9 construction 343:15 consult 72:11 consulted 104:24 consulting 168:16 218:9 241:7 259:11 319:15 consume 216:12 217:4 345:12 349:10 consumed 207:9 213:15 215:10 216:4 217:11,16 218:5 219:13,14 330:20 336:25 346:15 347:8,11 348:17 349:5 consumer 33:23 59:22,24 65:17 66:15 67:11 76:2 109:22 111:2 114:22 117:18 118:15 119:16 122:4 123:16 126:8,18 174:4,5 174:16,20 176:5 188:22 189:18 191:3,7,23 192:19 193:14,19 194:7 194:12 195:9,13 198:5,13 204:4 207:10,17 209:2 211:21 212:25	215:7,8,24 217:2 219:14,19 228:5 229:4,9,13,17 260:23 269:20 280:3 319:9 330:21 335:13 336:10,12,25 339:20 341:16 345:10 346:6 347:16 349:16 consumer's 69:18 211:22 338:13 340:5 348:9 consumers 8:20 25:3 34:8 35:11 53:8 57:17,24 63:5 68:8 70:8 74:6 78:14 92:3 112:14 120:8 126:9,19 158:17 173:21 174:7,15 186:3 204:24 205:24 218:15 219:10 223:24 235:16 319:18 321:5,9 324:17 332:2 334:21 342:25 343:2 345:24 349:3 consuming 195:17 260:4 consumption 194:2 205:23 211:22 215:2,14 215:23 216:7,9,17 216:20 217:22,24 328:9 329:5,13 331:11 332:19 334:14 335:23 342:12 343:15,25 344:22 345:17,20
--	--	--	---

[consumption - counted]

Page 14

347:6 348:10 contact 258:21 contacted 258:25 contacts 273:15 contain 29:12 34:25 39:2 contained 80:6 111:4 containing 8:17 39:13 40:24 111:2 118:5,11 121:14 contaminants 211:13 212:19,24 contaminated 43:24 61:6 110:22 111:17,23 contamination 60:8 110:16 111:13,14 210:14 contemplate 181:4 content 61:2 98:24 contention 188:13 188:21 274:6,23 284:11,12 309:8 contest 24:22 contested 59:22 158:9 165:10 173:22 contests 24:24 context 92:3 219:11 conti 23:20 24:5 24:11 continue 22:3 106:17 154:12 162:22 218:20 continues 134:7 contours 219:2 255:3 contract 129:5,22 130:11,13,18	155:24 285:13,22 286:9 291:10,18 291:22 292:2 298:16,17,17,21 301:18 310:6,9 312:8,23 contracted 97:4 132:18 133:7 297:24 299:4 300:8 302:6 309:7 310:20,21 contracting 128:21 130:3,8 155:2,17 156:16 286:2 289:10 290:22 291:14 292:23 309:18 313:11,22 316:8 contracts 118:3 130:14,19 156:22 189:23 298:16 305:11 308:16 310:5 contractual 134:15 310:23 313:15 contrary 71:19 133:3 277:10 300:11 345:22,25 contrast 164:5 293:18 contributions 239:11 control 95:13 146:22 147:20 186:9 189:24 190:2,9,14 191:4 267:22 268:16 controls 264:21 280:8	conventions 185:6 185:11 276:13 279:18 conversations 18:6 convert 159:16 341:23 converted 28:13 convey 262:3 convoluted 320:14 coordinates 270:19 273:14 copies 30:20 353:14 copy 16:3 37:5 38:22,25 coral 7:7 core 178:8 corp 6:5 corporate 3:9 correct 10:24 16:9 17:4 19:7 20:7 21:16 29:5 32:7 39:17 42:13 46:8 46:9 49:16,17,21 66:16 85:2,7 87:9 103:21 105:14 107:3 111:6 114:2 123:20,23 124:10 155:23 156:11 157:13,14 177:15 183:22 185:20 190:7 193:7 196:2 197:7 219:16 233:9,12,20 234:19 235:3,22 236:20 237:2 240:2,25 246:12 261:2 264:13 265:7,13,23 266:16,18 269:15	269:16,16 270:2,4 302:19 308:3 317:16 323:2 326:2 332:24 334:6,18,25 337:11 345:13 355:8 corrections 355:6 correctly 44:20 63:9 72:9 81:21 83:19 148:25 155:13 168:23 220:17 234:15,23 253:13 274:23 correspond 38:12 237:25 335:20 corresponded 341:25 cost 114:22 170:12 170:13 198:9,12 242:3 260:23,23 264:18 277:22,23 costs 198:11 counsel 9:12,22 15:15,22,23 16:19 16:22 20:12,14 21:12,14 27:11 40:10 42:9 53:4 53:15 54:3 78:5 102:6 103:25 104:20 107:19 153:6 180:25 231:9 236:13 278:24 321:16,22 322:7 349:22 351:4 353:14 count 40:4 46:21 159:19 238:13,15 347:17 counted 238:16 321:5
--	---	--	---

[counties - craft]

Page 15

counties 242:25	covered 224:3,19	103:1 104:1 105:1	211:1 212:1 213:1
counting 56:23	226:16,17 234:23	106:1 107:1 108:1	214:1 215:1 216:1
342:4,5	235:19 281:14	109:1,14,19 110:1	217:1 218:1 219:1
country 71:11	302:5	111:1 112:1 113:1	220:1 221:1 222:1
114:16	covering 102:7	114:1,11 115:1	223:1 224:1 225:1
counts 70:7,8	covid 196:11	116:1,12,14 117:1	226:1,13 227:1
county 249:13	craft 1:8 8:5,11,15	118:1 119:1 120:1	228:1,19,23 229:1
couple 21:8 26:19	9:6 10:1,10,15	121:1 122:1 123:1	230:1 231:1 232:1
39:14 60:24	11:1 12:1 13:1,10	124:1 125:1 126:1	232:3 233:1 234:1
101:15 129:2	14:1,2 15:1,20	127:1,20 128:1	235:1 236:1 237:1
176:20 320:16	16:1 17:1 18:1	129:1 130:1 131:1	238:1 239:1 240:1
322:21	19:1 20:1 21:1	132:1 133:1 134:1	241:1 242:1 243:1
course 12:7 19:23	22:1 23:1 24:1	135:1 136:1 137:1	244:1 245:1 246:1
30:9 87:14 92:24	25:1 26:1,21 27:1	138:1 139:1 140:1	247:1,8,14 248:1
104:18 121:7	28:1 29:1 30:1	141:1 142:1 143:1	249:1 250:1 251:1
145:12 173:8	31:1 32:1,17 33:1	144:1 145:1 146:1	252:1 253:1 254:1
180:8 189:11,25	34:1 35:1 36:1	147:1,7,11 148:1	255:1 256:1 257:1
194:16 204:14	37:1,4,12 38:1	149:1 150:1 151:1	258:1,6 259:1
214:22 216:2	39:1 40:1 41:1,19	152:1,7,9,12 153:1	260:1,8 261:1
221:10 261:11	42:1,23 43:1 44:1	154:1,24 155:1	262:1 263:1 264:1
281:6 289:15	45:1,3 46:1 47:1	156:1 157:1,5	265:1 266:1 267:1
292:17 298:20	47:15 48:1 49:1	158:1 159:1 160:1	268:1 269:1 270:1
345:25	50:1 51:1 52:1,22	161:1 162:1 163:1	271:1 272:1 273:1
court 1:2,16 9:10	53:1 54:1,25 55:1	164:1 165:1 166:1	274:1 275:1 276:1
9:14 38:6 59:5,6	56:1 57:1 58:1,15	167:1 168:1 169:1	277:1 278:1 279:1
65:9 70:22 75:14	59:1 60:1 61:1,23	170:1 171:1 172:1	279:4 280:1,20
77:2 93:4 94:22	62:1 63:1,9 64:1,7	173:1 174:1 175:1	281:1 282:1 283:1
97:23 116:18	65:1 66:1 67:1	176:1 177:1 178:1	284:1 285:1 286:1
117:10,11 124:7	68:1,23 69:1 70:1	179:1 180:1 181:1	287:1 288:1 289:1
180:25 198:15	71:1 72:1 73:1	182:1,6 183:1,10	290:1 291:1 292:1
230:10,12 320:22	74:1 75:1 76:1	184:1,3 185:1	293:1 294:1 295:1
321:13	77:1 78:1 79:1	186:1 187:1 188:1	295:9 296:1,6
court's 13:14 93:9	80:1 81:1 82:1	188:4 189:1 190:1	297:1 298:1 299:1
99:11,25 108:10	83:1 84:1 85:1,21	191:1 192:1 193:1	300:1 301:1 302:1
courts 58:20	86:1 87:1 88:1	194:1 195:1,12	303:1 304:1 305:1
320:20	89:1 90:1 91:1	196:1,16 197:1	306:1 307:1 308:1
cover 166:12,15	92:1 93:1 94:1	198:1 199:1 200:1	309:1 310:1 311:1
coverage 89:11	95:1,5 96:1 97:1	201:1,7,24 202:1	311:14 312:1
167:23 227:5,11	98:1 99:1 100:1	203:1 204:1 205:1	313:1 314:1 315:1
235:6,20 250:11	100:23 101:1,13	206:1,6 207:1	316:1 317:1,24
279:16	101:25 102:1	208:1 209:1 210:1	318:1,3 319:1

[craft - data]

Page 16

320:1 321:1 322:1 322:18 323:1 324:1,14 325:1,15 326:1 327:1 328:1 329:1 330:1,7 331:1 332:1 333:1 334:1 335:1 336:1 337:1 338:1,3 339:1,22 340:1 341:1,2 342:1 343:1 344:1 345:1 345:7 346:1 347:1 348:1 349:1 350:1 351:1 352:4 353:5 354:2,24 355:2,4 355:12 craft's 26:18 create 347:6 created 209:14 creating 245:5 credit 118:13,16 119:12 121:16 122:18 314:15 credits 115:19 116:3 117:23 criteria 329:2 330:19 332:23 334:4 344:17 critical 89:7 125:20 critique 25:19 cross 255:22 257:21 crosswalk 344:4 csv 28:11,23 29:6 culbertson 6:20 cumulative 206:14 207:22 208:11 209:8 318:13 331:19 337:14	curious 337:18 current 70:4 currently 69:10 169:5 227:2 243:18 customer 131:21 212:20 276:2 cut 43:11 58:3 104:14 138:21 145:7 147:12 150:11 236:19 cutting 147:14 cv 11:3 cvs 5:21 26:25 cw 105:7 d d 8:2 10:15 36:23 37:17 62:18 238:13,20 239:20 337:8 d'lesli 4:23 d.c. 17:6 d.stanoch 353:2 dallas 4:22 damage 123:10 173:21 237:25 254:25 damages 173:24 237:5,7 320:4 321:11 323:17,23 324:6,9,23 325:6,8 325:24 dan 5:9 dana 3:13 danced 271:2 darned 288:11 data 8:14 18:18 19:4,14,20,20,24 19:24 24:6,25 25:6,7,10,11,14,16 25:17 26:4,24	27:16,18,21,22,25 28:4,5,14,16 29:20 29:22,23,24 30:2,3 30:8,11,14,17 32:4 32:21 33:6,10,19 33:20,20 34:3,5,18 34:20,23 35:8,23 35:25 36:4,13,19 40:9,18 55:23,25 57:5 62:25 63:14 63:22 64:24 65:2 65:3,4,7,15 66:14 67:3,5 68:10,11 69:4,14 70:18,21 71:5 72:2,20 73:2 73:18 74:2,10 75:4,18 77:12,12 77:15,22,23 78:2,8 78:19,20 80:13,16 80:20,24 81:9 83:5,15,16,20,23 84:2,4 90:22,22,24 93:5 94:2,8 95:11 95:11,21,24 96:3 96:11,14,16,17,22 96:22 97:6,9,12,19 97:19,24 98:19 99:5,13,16,18,18 99:23 100:4,8,11 111:19,20 114:14 115:17 116:4,5,7 117:20 118:18 123:20 124:3,4,11 124:18 125:6,10 125:15,17,25 126:6,14,17,22,24 132:12 133:5 135:17 136:15,16 137:8,9,18 138:2,5 138:5,13 139:11 139:12,25 140:2,3	140:16 141:25 142:8 143:14,14 144:18,23 146:15 146:16,23,24 148:5,6,10,13,17 148:24,24 149:4 149:11,13,22 150:13,15 158:7 159:7,12,24 160:9 160:11,20 161:12 161:14,18,20,22 161:23,25 162:6,7 162:10,21 163:5,8 163:14 164:2 165:4,8,18,25 166:7,10,20,21,23 167:22 168:4,9,21 169:6,13,15,25 170:8,9,20 171:2,9 171:10,12,15 172:2,11,19 173:5 173:10,15 174:12 174:17,19 175:7,8 175:22 177:13 178:9,10,22,22 184:25 185:9 186:14,17 189:22 189:24 191:5,20 192:19 195:23 196:17 197:5,8,11 197:13,16 198:7 198:18 201:9,14 214:15,16 215:2 217:9 218:3 223:20 226:3 227:25 228:7 229:16 233:11 234:2 236:9 238:2 238:10 239:15 240:3,10,15,18,23 241:14 242:9
---	--	---	---

[data - definitionally]

Page 17

243:10,14,16,21	343:11,11 346:9	dealing 226:24	defendant's 226:3
244:5 245:24	346:16,23 347:11	deals 183:11,22	227:11,16
246:10,10 249:17	348:4,14	220:9	defendants 8:10
250:24 251:18	database 94:21	dear 116:13	27:3,13 29:25
252:2,14 253:2,4	127:9 273:4,8,21	decades 181:17	33:24 35:19 40:20
254:6,9,13,19	databases 138:15	december 102:3,8	43:21 48:5 69:20
255:3,5,6,7,14,23	178:7	102:12 103:4	69:21 70:9,14
256:11 257:11,16	dataset 42:15	decide 65:9 180:25	75:19 76:5,5,24
257:22 260:18,20	date 16:7 22:21	190:16	78:12,17 108:11
261:10 264:8	35:22 176:22	decided 77:2	110:12 165:17
269:6 271:3,12,15	184:13 225:22	345:21 347:8	186:18 192:9,10
272:10,13,14,21	280:5 347:19	decides 65:9	198:4 200:11
272:23,24 273:24	348:9 349:18	deciding 268:7	202:2 203:2 205:5
273:25 275:10,18	354:24 355:12	decision 98:16	220:9,11,13 221:4
276:4,14,14,18	dated 102:2	100:2 238:3,8	221:14 222:2,19
277:2,9,17 278:3,5	196:23	decisions 108:10	223:7,10,13
278:15,17 279:11	dates 70:11 186:8	314:15	226:15 227:24
279:15,25 280:11	190:23 206:2	declaration 8:15	229:21 230:22
280:23 281:13,17	dating 194:19	23:5 62:23	258:12 306:23
281:20,22,24	dave 37:24 61:23	declarations 78:18	332:12 344:3
282:4,4,8,12,12,16	116:24 151:11	146:3	defense 27:11
282:19,20 283:2,8	196:9 200:6 203:8	declare 355:4	349:24
283:23,24 284:7	295:5 322:4 350:8	decompose 148:23	define 76:23
284:22 293:3	david 2:8 351:3	decomposed 229:6	133:17 209:13
294:4,9,13 296:12	353:1	304:16	326:9
299:12,16 300:19	davis 4:23	decomposition	defined 90:21
301:7,20 302:9,11	day 12:14 105:19	142:4	113:12 197:4
302:24 304:3,16	125:10 145:6	dedicated 202:4	202:5,16 208:22
304:21 305:5,13	159:18,19 185:25	deduct 348:10	defining 77:22
305:23 306:5,10	213:8 277:6	deductible 141:19	208:20
306:19,20 307:11	306:25 341:21,22	deemed 79:2	definitely 38:18
307:12 308:13,23	341:22 347:21	355:6	321:25 324:19,24
309:9 314:21	352:15 355:15	default 140:18	definition 87:11
315:2,5,14 318:5	days 330:24	defend 307:2	89:25 121:13
320:25 324:16,20	333:11,20 338:24	defendant 18:22	188:19 202:2,4,25
324:25 325:3,10	341:23 344:20	19:3 48:23 49:4	203:10,14 207:8
328:11,18,18,21	347:22 353:17	110:20 165:8,8	218:13 226:25
333:7,9,22 334:2	dc 5:7	202:6 225:10,17	237:22,24 243:2
334:16 335:2,3	de 7:6	226:16 227:12,19	255:4 332:5 333:3
338:23 340:13	deal 64:20 213:3	229:11 230:4,23	definitionally
341:20,24 342:11	216:25 312:14	231:2 258:12	287:15

[definitions - direct]

Page 18

definitions 8:19 53:6 63:7 219:3 253:23 329:22,24 delay 127:19 delineate 96:14 97:7 148:12 delineated 91:20 delineation 96:15 deliver 277:15 delivering 163:9 314:6 delivers 72:14 delivery 234:25 demonstrate 277:2 342:13 demonstrated 162:2 denies 304:20 denominated 267:7 depend 189:22 dependents 226:4 depending 93:2 121:4 depends 119:11 176:9 212:9 deponent 353:13 355:3 deposing 353:13 deposition 8:11 9:5 10:5 11:10 13:5 15:2,19 16:2 18:13 20:15 23:25 36:25 37:19 40:2 44:8 46:24 66:11 70:13 128:3 129:16 145:22 152:15 180:8 196:5 351:7,10 352:7	depositions 11:2,5 derive 214:7 derived 253:9 describe 91:5 146:10 148:6 271:21 312:4 326:10 described 30:15 52:16 53:12 55:24 73:11 91:10 96:12 115:13 139:3 140:4 148:9 185:13 226:18 227:10 257:13 273:19 286:5 293:15 336:16 338:23 347:14 describes 25:24 describing 42:25 220:6 246:5 253:2 253:12 293:9 311:17 description 8:9 53:20 97:18 117:23 139:10,16 139:16,17 224:5,7 274:25 276:5 278:19 298:23 301:10,13 326:15 334:24 descriptions 244:6 293:22 descriptive 293:2 293:5 descriptor 294:10 design 131:20 designated 105:7 119:20,24 241:10 designation 80:12 80:22,23	designed 43:22 150:2 283:4 desktop 17:12 despite 342:10 detail 53:22 80:2 103:11 197:6 223:5 details 16:14 169:9 273:13 determinable 307:8 determination 146:7 221:17 determine 61:17 111:16 122:2 141:14,18 166:25 191:6 194:6,11 209:8 211:21 216:19 217:10 233:15 279:15 292:6 334:3 335:24 337:13 340:4 342:15 determined 75:15 111:22 123:9 determines 236:14 determining 59:5 208:10 313:7 developed 140:7,8 178:8 181:16 developing 233:14 device 17:14 163:7 devices 17:7 diagram 136:13 139:3 dictionaries 276:15 277:17 dictionary 280:11 differ 90:12 143:13 248:16	differed 211:19 difference 92:14 160:15 differences 61:5 91:8 146:9 270:15 276:12 277:25 different 12:2 31:12 42:3,3 59:11 73:18 84:6 90:7,18,20,23 91:13 92:3,17,25 94:20 97:17 98:10 112:21 135:19 164:13,16 167:7 172:23 187:15 188:5 194:21 197:14 204:6 205:14 207:20 225:14 236:7 266:3 270:15,18 276:3 281:19 297:5 298:10 303:11 314:22 315:4 325:5 327:3 332:7,7,11,16 333:18 335:21 343:9 differentiate 218:14 268:4 271:8 272:8 differently 90:21 277:21 difficult 21:6 71:20 225:2 276:8 difficulty 313:7 diffuse 161:6 dig 72:24 digit 50:17 digits 51:4 direct 52:22 57:13 135:23 136:23
---	---	--	---

[direct - drew]

Page 19

156:2,20 304:23 directed 44:16 directing 55:5 direction 238:10 271:19 directions 271:20 directly 35:16 70:20 71:10 77:8 130:8,12 135:25 149:22 156:15 185:2 204:5 234:8 234:10,15 235:10 235:16 254:11 255:19 269:7 285:22 286:3 287:8 291:10,15 304:7 316:20 disagree 58:20 disclose 198:18 disconnect 44:16 discount 158:16 253:21 discovery 10:6 30:10 discretionary 268:17 discuss 63:22 78:4 100:23 111:20 131:16 169:8 196:17 240:11 discussed 63:17 120:17 125:17 145:15 229:25 discusses 55:22 56:2,3 123:19 discussing 64:24 119:13 128:19 discussion 146:2 178:6 190:8 217:22 297:22 298:2	discussions 208:19 dismiss 105:17,23 106:11,20 108:4 108:11 dispense 186:3 206:3 348:13 dispensed 75:23 114:15 156:21 160:2 165:12 174:8 186:6 191:2 193:13 206:2 207:12,13,15 215:6 217:11,16 247:2 283:14 346:15 dispenses 166:4 283:13 dispensing 69:5 163:25 166:3 215:16 216:16 217:23 280:4 dispositive 99:12 110:21 dispute 24:22 disputes 69:25 304:14 disregard 307:20 distinct 256:24 distinction 89:7 91:4 112:3 258:2 distinguish 31:21 113:6 distributed 43:23 203:16 distribution 112:13 178:17 distributor 204:2 district 1:2,3 diverse 64:20 divide 83:6	divides 282:7 divulge 87:5 90:16 98:9 167:6 168:15 169:8 208:16 218:7 docket 107:13,15 107:23 document 14:15 14:23 15:7,9 17:13 20:21,22,24 22:10,19 26:22 29:2 31:3 47:8 85:22 202:15,19 203:21 212:3 329:15 documented 121:8 documents 13:12 15:13,23 20:4 21:5 22:2 23:2 29:15 43:4,14 103:7 104:8,11 172:4 doing 20:18 37:13 130:4 132:16 151:23 170:25 189:10 221:10 224:8 229:20 252:8 254:8 255:11 314:18 320:23 337:17 341:7,10,15 342:4 dollar 201:12 283:17,19 dorner 3:11 8:5 9:20,22 21:17 22:4,8 26:6 32:8 36:20 37:13,24 38:19 44:22 47:6 49:22 54:21 61:19 62:17,19 68:15,16 84:8 106:13,16	108:17 109:2,13 116:24 117:4 147:11 150:25 151:6,11,18 152:5 152:9,10,17,21 153:2,9,12,15,16 153:20,22 154:2,6 154:14,17,20 156:24 181:25 182:4,14,20 196:3 196:8,13 200:4 201:18 202:17 203:7 217:16,20 228:12,17 231:22 232:11 280:15,17 295:4,21 315:24 321:15 322:3 323:11 329:18,19 350:8,19 dorsey 6:12 dosage 174:8,23 205:25 207:12 329:4 333:10,20 335:17 336:25 338:25 339:13 dosages 332:16 338:12,17 dose 183:16,22 338:6 339:20 double 255:25 doubt 174:14 dr 23:20 24:5,11 24:21 drafted 227:2 draw 106:24 drawing 106:20 254:8,11 drawn 106:9 233:10 drew 3:11 9:22 151:8 326:8
--	--	---	--

[drew - ends]

Page 20

329:18 350:16 drill 72:15 driven 133:5 182:19 drop 136:10 drug 34:11,13 45:16,25 50:5,23 55:19 60:3 61:10 69:13 98:22 99:21 99:21 111:2 113:11,12 114:2 115:7 118:8,11 135:11 141:16 160:6,17 163:25 166:3,3 170:13 183:12 189:8 192:5 196:21 216:6 239:9 240:5 250:11 260:23 288:7 289:14 306:24 320:5 333:9 345:24 349:9,20 drug's 52:13 drugs 8:17 16:11 34:7,8 40:24 48:3 48:23,23 49:5 118:2,6 121:14 164:19 167:24 183:23 215:6,9,10 216:11 321:7 dry 153:25 dscsa 183:11,14 184:6 185:8 duane 3:4 225:16 225:19,24 due 110:15 duly 9:17 352:6 duplicate 28:20 duplicated 25:5	duration 187:16 330:14,21 331:7 dwel 195:11 dynamic 317:8 e e 2:2,2 3:2,2 4:2,2 5:2,2 6:2,2,24 7:2 7:2 8:2,8 32:19 33:18 47:8 124:8 354:3,3,3 earlier 45:19 65:8 96:7 127:23 128:19 129:16 131:13 148:9 161:14 167:24 193:8 218:22 260:8 277:6 278:3 281:15 318:21 322:23 326:8 343:13,18 345:15 easily 67:3 117:19 122:10 216:3 227:2 236:12 easy 25:13 236:4 251:21 265:8 341:12,24 349:6 echo 47:9 economic 59:13 173:21,23 210:18 210:21 239:17 319:10,18,20,21 319:23 323:24 324:9 325:24 effect 88:13 effective 184:13 185:11 effectively 25:5 100:7 139:11 253:15 255:25 efficient 67:16 69:3 74:3 180:9	efficiently 283:4 effort 119:21 eight 21:10 109:16 109:18 123:24 either 23:25 40:19 50:15,15 72:20 116:9 120:7 132:17 155:18 171:12 189:14 198:7 201:11 203:16 217:9,11 218:2 234:24 285:19 286:7 293:3,16 300:21 304:5 334:11,23 elected 287:8 electronic 17:7,14 25:3 34:14 55:16 73:2 80:13,16 96:21 132:2 306:10 electronically 13:13 72:2 121:3 121:7 185:10 186:10 306:2 element 58:9 125:20 189:10 203:24 elements 19:16 25:4 35:23 95:18 95:21 113:14 137:8,10 143:18 269:14 271:13,25 272:25 333:8 eligibility 141:14 eliminate 61:14 223:23 229:2,4,17 229:18,19 255:24 else's 214:11 email 17:23 150:21	embedded 118:2 emeryville 17:3 emp 246:22 emphasize 61:8 66:10 emphasizing 65:21 employed 225:9 employee 221:11 222:7,11,11 224:18 225:5,19 226:23 227:12 243:17 245:18 248:3 249:9,21 251:7,22 259:3 287:7 288:22,22 employees 221:15 224:12,14,22 226:15,19 227:18 230:22 247:3 employer 89:21 101:5 139:17 276:6,7 287:20 288:5 290:13 303:21 employer's 230:2 employers 177:19 employment 134:20 231:15,17 empty 153:17 enable 97:13 encompass 64:9 64:20 97:3 encompassing 66:4 encourages 55:20 ended 78:14 ends 62:6 109:6 182:24 232:14 308:23 351:10
--	---	---	---

[enforceability - exchange]

Page 21

enforceability 76:11	119:20,22,24,25 128:16 133:7,8	establish 194:7 237:19 332:22	exactness 68:4
enforced 184:16	134:9,15 135:24	established 178:18	examination 8:4 9:19 322:5,16 352:5
engaged 278:4 320:18 327:21	220:23 227:5,6 234:10 242:23	179:17 236:9 250:18	examined 9:18 194:6
engine 273:4,10	248:22 256:20	estimate 21:7	examining 80:8
english 188:7	257:8 265:16	164:5 172:9	example 27:18 28:6 36:11 53:23 64:14 81:2 107:18 118:15 120:23 145:2 156:19 161:8 162:25 163:9 172:20 176:17 181:10 184:17 191:15 198:10 218:15 222:7,10 224:18 236:6 246:15,18 249:13 253:7 255:18,20 270:18 275:25 283:13 293:14 298:17 303:6 311:23,24 312:4 317:4 320:24 331:3 335:8 337:3,8,9 339:9 341:11
enormous 161:17	279:19,21 286:2,9	212:23 213:6,12	
enrichment 202:3 203:2 204:13	292:24 300:8,20 313:23 334:21	213:14,19 214:8 245:11	
enrollee's 234:11	entity's 133:10	estimated 52:6	
enrollees 88:7	entries 28:8	estimates 212:14	
ensure 89:22 136:19	entry 105:6,25 106:2,18,25 275:5	estimating 40:7	
ensured 275:7 287:25	enumerable 178:15	estimation 214:25 299:11	
enter 13:24 38:10	enumerates 165:9	et 353:4 354:1 355:1	
entered 198:16	enumeration 55:6 127:12	evaluate 53:5	
enterprises 249:14	equals 282:20	evaluates 55:23	
entire 14:15 57:4 117:25 118:8 123:11 172:13	equation 339:23	evaluating 279:24	
entirely 25:13 91:13 185:11 194:4	equivalent 157:18 159:17 187:23	event 150:16	
entirety 138:4 158:17	errata 39:13,20 353:11,13,15,17	everybody 13:9 67:23 109:14 148:7 278:8	
entities 9:23 25:6 25:21 71:22 82:2 86:24 88:10 157:9 161:24 168:5 220:10,20 221:21 223:8,11 229:22 233:24 234:5 238:17 243:7 244:15,16 249:6 251:2 258:15 259:20 288:17	escrow 314:9,13 314:15	everybody's 142:21 175:7 295:22	
entitled 1:14	escrowed 314:11	everyone's 37:14	
entity 47:23 48:22 76:18 88:14	esq 2:8,9,18 3:11 3:12,13,14,15,24 4:8,9,16,23 5:8,9 5:17,24,25 6:8,16 6:24 7:8,15 353:1	evidence 10:8 99:5 197:22 199:5,14 201:2 210:8	examples 98:17,19 310:14 337:7,20
	essential 25:4 67:6 67:13 84:7 121:10 141:8 143:11 149:17 161:16 162:23 170:21 189:10 191:3 275:9	exact 41:22 83:18 102:20 114:17,19 212:18,24	excel 8:22 28:9,12 233:3 247:12 337:15 341:6
		exactly 14:12 31:19 40:22 75:19 75:21 163:14,15 165:11 167:17 172:24 236:3 265:19	excellent 13:2 exception 35:9 224:17 286:4 287:5 289:3 290:20
			exceptions 177:18 exchange 114:13 287:14 294:22

[exchanged - fact]

Page 22

exchanged 13:19 261:10,14 exclude 221:8 227:18 240:12 243:9 250:4 255:14 258:12 excluded 86:24 88:14 224:4 230:16 237:6 242:25 248:22 249:5,6 252:13 excluding 79:11 82:2 245:24 exclusion 87:11,22 87:24 235:24 256:4 259:8 320:11 exclusions 53:7 56:3 220:6,8 231:10 233:24 249:4 250:25 251:6 258:9 259:17 320:8 exclusively 191:11 excuse 38:6 42:22 130:9 136:20 181:22 184:20 205:3 209:22 344:24 executed 133:19 249:19 326:13 exemptions 184:18,22 exercise 41:8 46:23 51:18 59:21 133:5 219:9 251:19 252:8 277:4 336:11 341:4,6 342:3 343:5,12	exercises 27:17,24 170:2 exhibit 8:10,12,13 8:15,16,18,19,22 13:23,24 14:19,22 21:18,20,21 26:15 30:25 31:2,23 32:3,10,11,15,19 33:9,18 34:24 36:22,24 37:2,15 38:7 42:22 47:10 47:11,18 48:21 49:24 52:20,21 62:14,17,18 64:12 84:17 101:7,11,12 101:22,25 105:3 109:15 183:7 201:19,20,22 202:8,24 220:4 232:21,25 233:2 235:25 236:2 238:13 240:6,8 247:7 248:2,8 249:19 258:5,6,10 258:13,18,18 295:25 329:16,16 329:20,25 335:22 350:10 exhibits 8:9 14:3,7 14:10 18:6 37:15 38:3 39:2,4 exist 36:19 81:9 170:2 189:12 190:15 275:11,12 305:9 existed 244:7 existence 25:22 82:17 259:19 exists 25:8 72:2 163:6 304:2 306:10 324:20,25	expect 100:13 116:8 122:7 158:2 167:20 189:21 230:11 288:21 expected 25:13 35:24 40:25 96:20 166:11,14 313:14 316:7 expedite 268:18 expenses 71:24 expent 78:10 experience 219:19 230:10 294:12,15 299:2 expert 1:8 8:15 10:22 23:4,5,15,19 29:11 31:14 32:19 40:12 105:2 234:21 236:23,24 241:10,16 310:16 327:16 expertise 107:8 210:16 experts 237:5 327:17 expiration 186:8 190:23 expired 110:13 194:18,20 explain 12:3 193:22 256:17 279:9 explained 249:22 256:9 276:14 277:5 301:21 303:18 305:23 318:20 explanation 81:13 149:20 228:18 explicit 42:16 87:11 91:2 171:22	294:9 306:5 explicitly 50:16 306:18 exponent 124:7 exposure 213:7 214:8 318:13 express 27:2 53:25 58:21 223:22 291:12,14 312:19 324:23 expressed 59:3 107:9 108:4,9 expresses 25:8 expressing 60:23 76:19 324:6 extensions 184:12 extent 14:13 15:17 53:13 58:13 66:2 87:6 126:21 193:9 204:7 207:5 239:6 242:17 248:19 324:12,15 extract 174:16 176:5 extraordinarily 150:24 extremely 127:4 130:23 131:10 exuberantly 162:2 eye 107:22
			f
			f 9:17 10:15 101:12 faced 75:18 facially 304:2 fact 11:14 44:18 46:13,15 47:2 51:16 91:23 92:16 93:8 110:20 111:24 120:20 122:2 123:15

[fact - firm]

Page 23

129:22 139:20	familiar 37:11	283:14 284:6,22	filed 146:3 159:14
143:11 158:4,14	206:9,12,15,18,23	285:12,25 286:12	files 19:15 25:3
158:21 163:6	249:14 310:8	286:20 288:13	27:11,15 28:9,11
165:2 186:20	311:19	289:23 290:19,25	28:20,23 29:6,10
201:13 215:10	family 230:13	292:4,5,15,19	29:19,21 30:15,18
217:3,4 239:2,4	fantastic 107:19	293:5,6,7,10,11,12	36:11 70:12
243:8 252:11	far 48:8 90:5	297:5,8 298:15,20	filing 123:7 230:15
288:15 289:8	100:14 102:25	299:25 300:7,14	fill 70:17 126:23
304:14 333:12,19	103:25 117:12	301:14,15 308:20	280:5 344:15
factor 110:6	312:17,24 346:9	308:20 311:5	347:12,21 349:19
219:15 330:19	fashion 175:21	336:21	filled 126:12
348:6 349:15	faster 247:24	fields 24:25 35:20	127:13,13 165:6
facts 24:5,6,23	fault 278:10	77:22 95:24 99:25	195:8 334:9 343:7
25:13 59:4 76:3	favorable 178:16	133:25 134:23	344:19 346:6,17
92:25 98:15 99:10	230:19	135:20,22 136:5	fills 126:20 332:22
144:15 197:22	fda 44:3	136:15 137:15	335:19 340:3
199:5,14 201:2	feasibility 320:23	138:7 139:7,13,18	final 112:13
210:8 305:12	feasible 34:15	140:9 146:7 147:5	169:22 225:22
329:10 346:22	february 1:10 9:3	149:24 150:13	255:11 320:19
factual 93:9,10	102:2,7 353:3	170:9,21,22	finalize 321:12
98:2 173:18	federal 10:8 93:19	246:10 261:14	finalizing 39:19
factually 93:10	234:4 249:5 250:3	275:11 276:4,10	financial 71:21
fail 88:11	250:3,5,7,10,13,14	277:12 280:12	145:4 314:3
failed 125:19	250:16,19,21,25	282:10 283:3,13	337:16
failing 117:18	251:5 256:12,13	292:16 293:2,21	financials 159:15
fails 353:19	256:14 257:7,8	294:10 297:18	find 44:19 107:22
fair 12:4 18:9,10	federally 238:14	298:10 309:9	227:13 259:24
23:24 38:17 45:9	fee 234:17 235:2,5	fifth 265:5	289:3 296:5
56:9 81:10 102:13	235:16,24 236:19	figure 51:7 80:9	299:23 301:24
103:20 113:5	237:6 249:7 250:2	89:22 94:13	fine 12:22 15:8
128:17 187:2	250:23 280:4	132:14 146:19	64:21 66:19
195:19 203:4	feel 193:21 247:8	147:21 149:23	150:25 182:10
222:15 239:23	feeling 317:24	156:24 166:13	187:20 232:8
319:25 328:23	felt 251:13	174:21 261:7	finish 262:9
fairly 203:12	field 19:15 28:6	265:4 271:11,24	finished 40:19
falanga 4:4	72:21 94:4 98:20	340:6	104:15 136:7
fall 203:13 204:8	163:14 179:18	figures 325:9	183:16,22 267:11
205:6 227:8	196:24 264:22	file 27:7,20 28:4	firm 7:5 9:9,11
falling 87:23 339:7	268:9,10 274:12	52:16 72:21	107:12 190:23
falls 191:7	275:17 279:22,25	146:13 177:17	200:2 225:16
	280:22 281:4,10		

[first - formula]

Page 24

first 9:17 27:10 32:13 35:21 44:5 47:22 48:10,15,17 49:20 50:17 51:4 51:15,20 53:11 71:3 77:11 88:11 88:15 89:4 93:18 95:5 105:24 112:16 115:12 116:3 127:24 128:14 133:23 136:20 146:17 152:10 157:11 160:10 164:4 168:25 172:17 173:14 178:13 220:14 227:14 256:10 257:5 265:3 271:5,7,23 279:14 280:25 287:10,23 296:14 309:21,21 313:25 336:8 five 42:22 55:25 56:11,20 61:22 84:16,17 99:3 108:22 151:7,13 154:4,7 168:11 231:25 232:7,19 271:23 295:6 321:23 322:2,6 344:20 fixed 235:5 flag 256:12 257:6 257:17 304:5 339:3 flip 26:18 flipped 244:25 300:16 floor 4:6,14 5:14 6:14,22 38:22	199:18 florida 3:10,23 7:7 flow 271:19 314:14 focus 62:21 63:11 84:23 112:5 114:10 115:11 123:25 133:23 136:12 146:17 205:21 221:23 258:19 264:4 318:8 focused 107:8 115:20 174:24 folder 14:5,14 17:13 32:11 33:2 37:15 62:18 329:17 follow 52:8 175:9 274:7 345:7 following 146:7 225:6 283:19 316:5 follows 9:18 61:10 footnote 39:14 160:13 177:6,7 178:5 footnoted 25:9 forced 199:25 forcing 154:8 200:4 foregoing 355:5 foresee 179:24 forget 144:8 320:11 350:9 forgive 247:17 forgot 77:9 258:7 form 22:20 33:14 34:15 36:9 41:18 43:8 46:18 49:9 50:7 51:11 53:18	54:10,18,22 56:15 58:12 59:17 60:18 63:18 64:3 65:19 68:13,18 69:17 73:15 74:18 77:18 79:6,14 82:5,22 88:20 90:14 92:7 93:12 98:4 103:6 108:14 110:2 111:8 114:4,25 115:23 118:21 120:12 121:18 122:8,21 124:21 129:8 130:16 132:21 135:4 136:3 137:2 140:13 143:4 145:18 150:5 155:8,21 156:5 157:22 158:16 162:17 164:15,24 168:13 169:17 171:18 172:15 175:12 177:8,12 177:17,21 178:2,8 178:21 180:19 183:19 186:25 188:2,17 189:2 192:22 195:25 197:20 199:2 202:10,14 203:20 204:11 205:9 207:2 208:5 209:12 210:6 211:25 213:21 214:20 215:18 216:3,14,19 217:14,19 222:25 226:8,22 228:21 230:8 231:5 237:12 239:22,25	240:17 242:13 243:23 248:14,24 252:18 254:21 255:16 256:7 269:12 270:13 275:3,21 276:22 282:2,23 284:14 284:25 286:23 291:3 292:8 298:12 299:6,19 300:24 302:13 304:25 308:5,14 309:11 311:8 313:19 315:21 316:23 319:13 320:13 323:4 324:2,5,11 326:4 326:24 327:8,24 328:14 329:8 331:21,24 333:2 336:4 337:23,23 340:19 342:19 343:20 345:2 346:20 348:19 formalities 11:22 format 27:25 28:12 29:6 30:11 143:15 252:24 formats 27:20 98:20 185:8 formatting 29:12 29:13,16 former 337:15 forming 43:6 108:2,8 124:12,15 177:13 forms 174:23 212:13 225:4 261:9 formula 335:22 337:20
--	---	--	--

[formulary - getting]

Page 25

formulary 92:12 135:12 141:16	53:13 263:24 273:14 277:5	290:15 293:4,19 296:10 297:23	general 19:9,17 107:5 119:17
formulation 113:14	293:17 298:22	300:19 303:22,23 304:10,12	158:13 159:22 220:19 286:5,16 286:18
forth 142:11 202:24 331:18 352:6	fully 31:18 71:19 74:12 76:6 83:3 86:22 87:12,16 88:4,16 89:3,15,21	funder 76:15 funder's 75:7 funding 72:17 80:11 99:7 223:14 238:16 242:16 244:5,8,11 245:3,7 245:12,19 248:16 253:24 258:22 259:2,19 266:12 268:25 273:16 285:21 287:6 289:13,15 291:9 291:17 296:25 297:3,16 300:12 301:17 305:4 308:19,24 316:10	generalize 93:3 generally 11:4 18:17 36:13 42:25 52:3 58:17 64:24 65:14 94:17 96:20 98:25 159:2,5 171:8 190:24 206:13 233:13 240:2 274:19 285:6 289:9 305:6
forum 319:22 forward 335:13 found 277:24 321:13	93:6 97:25 98:21 122:3,4 171:11,24 184:7,10 222:14 242:16,18 248:11 267:15 269:8 280:23 287:16,25 288:8,11,21 289:8 293:3,15,16,17 294:24,25 296:11 303:22 314:19 317:15	generate 29:21 30:5 33:17 40:4 71:22 99:19 132:2 135:11 140:3 143:19 304:23 generated 30:4 32:18 34:2 46:21 46:22 145:11 159:9,10 264:17 generates 119:16 304:15 generating 29:22 181:2	
foundation 197:21 199:4,15 200:24 210:7 213:24 301:2 302:16 309:13 311:10 336:6 345:4	function 55:15 84:7 143:16 144:19 149:18 198:15 207:11 functional 207:8 216:8 functionality 277:16 functionally 208:22 functions 143:6,11 fund 312:7 fundamental 324:21 fundamentally 26:3 funded 72:7 75:5,6 76:18 99:4 134:19 221:2,3,7,16,25 238:14 242:21 243:6,18 244:19 248:12,20 250:13 255:19 280:23	further 35:15 53:22 60:2 107:25 113:16 114:6 125:22 148:23 169:9 197:6 223:5 225:19 234:6 352:9 fuzzy 176:17	generation 55:25 generic 44:3,8 92:15 218:16,18 283:15 generics 219:5,5 generis 143:22 geoppinger 6:8 germane 91:16 115:8 156:10 328:5 getting 71:14 84:3 104:21 113:17 126:2 148:7
four 15:4 20:19,23 55:21 77:8 84:22 99:3 125:23 172:12 183:5 231:10 232:14 265:3 271:23 314:22 337:3,7 fourth 200:9 201:7 205:22 free 247:8 frequency 158:5 frequent 298:7 frequently 72:19 77:21 116:4 165:2 244:19 245:19 253:23,25 297:11 297:12,13 friday 12:15 front 47:16 99:23 231:9 froze 116:12 fulbright 4:19 full 10:13 22:18 36:15 52:25 53:12		g g 232:25 gables 7:7 game's 306:17 gannon 4:9 gaps 126:22 garbage 215:10 gated 173:2,3 gathered 94:8 gathering 305:13 307:7 gears 177:2 231:24	

[getting - going]

Page 26

149:22 190:3	74:23 77:19 79:19	256:8 258:2,4,17	107:11,16 109:7
261:23 266:2	82:11,23 84:12,16	259:23 260:5	117:5 119:25
286:15 304:5,18	85:9 88:9,18,24	261:6,15 262:9	122:16 131:2
305:20 307:25	89:4,20 91:3,12	266:20 267:12	134:6 137:17
give 11:4 19:9 52:5	92:10,22 93:17	270:5,24 273:7	139:7 144:21
70:10 167:15	96:2 100:18	276:24 278:9	145:5,6,7 148:4
170:11 176:13	101:11,21 103:8	280:10,11,13	150:21 151:10,10
184:24 287:4	105:3 106:17	282:25 285:5	151:12 152:23,24
297:14 304:11	108:15 109:16	288:2 290:6,6	152:24 154:21
given 11:2 13:12	110:4 111:10	291:7 292:13	158:24 165:22
23:6 24:16 53:5	114:8 115:4 119:2	295:2 301:3	167:16,17 182:14
59:19 67:9 75:20	119:10 120:16	302:18 305:2	182:25 184:2
113:25 116:7	121:22 123:3,24	306:12 307:9	186:13 187:22
118:16 122:4	126:7,18 127:16	309:16 311:14,22	188:11 195:16,22
123:6 126:12	129:9 132:24	312:23 313:12,20	203:12 205:15
167:2 174:3 179:2	133:21,22 137:5	316:18 318:18	223:13,23 224:23
209:2,21,23 214:8	141:4 149:20	320:15 321:19	224:24 225:7
236:4 247:14	151:2,7,9,17	322:7 323:6	226:20 231:22,24
270:17 339:19	152:17 153:5,17	324:14 325:15	232:15 236:6,7
352:8 355:9	153:18,22 154:3,7	326:5 327:10	247:12,22 249:12
gives 166:18 314:7	154:18,21 162:19	328:16 329:11	260:9,12 261:15
338:24	163:18 164:25	330:6 333:6 336:7	261:17 265:9,15
giving 167:14	166:8 168:25	338:3 339:17	266:6,11,15,20
221:14,16	170:21 175:19	340:25 342:21	267:15 268:6,21
glad 22:24	176:16 177:2,3,3,6	346:25 350:9,12	268:24 269:25
glean 267:19	180:22 182:2,15	350:16	272:3 279:9 280:7
glossary 253:16	183:8 187:20	gobbled 161:10,11	283:19 285:10,24
go 13:13,22 15:4	188:3 192:23	goes 30:18 39:3	286:2 287:3,16
15:20 22:11,11	195:20 196:13	159:2,6 160:22	288:2,23,24
24:8 26:3,11,15,17	198:2 201:7,18,20	224:20 227:6	289:25 290:6,24
32:13,14,25 33:15	201:21 203:10,21	233:18 244:7	291:13 292:20
36:22 38:20 40:15	205:10 210:11	245:5 264:4,4	294:5 295:4,7,15
41:19 42:21 43:9	211:8 214:3	310:25	302:24 303:7,9
43:17,18 44:13	215:20 218:10	going 9:2 12:8,13	304:7 305:6,7
45:8,13 46:19	220:2 222:6 224:8	13:4,5,18,19 15:10	308:12 312:7,9,12
47:7 49:10 52:19	225:11 226:13	17:21 21:24 37:8	312:13,14,15,19
52:20,20 53:2	227:14 228:24	50:21 52:4 61:20	312:21 314:2,6,20
54:20 56:18 58:15	232:24 237:16	61:21 62:7 73:5	315:8,18 322:11
59:18 61:6 62:13	238:10 240:7	84:24 93:21 94:12	329:20 330:10
64:7 66:12,19	241:8,21 244:5,22	95:4 96:25 97:16	331:12 332:18
68:23 71:9 73:16	245:21,21 251:12	97:20 105:4	339:5,18 340:3

[going - help]

Page 27

345:23 347:15 349:8 350:12,22 goldberg 3:12 200:13,14 golf 233:2 good 61:24 62:2 68:4 107:22 168:2 215:3 254:24 259:21 280:16 295:6 306:22 337:15,17 350:18 gordon 5:12 gosh 245:10 345:23 gotten 10:9 government 25:21 55:17 234:5,9 238:17,21 239:19 242:17,21,22,23 243:6,7 244:15,16 244:21 245:5,8,9 245:18 249:6 250:5,7,16,19,22 256:12,14,15,20 257:7,7 governmental 245:25 248:21 251:2 256:4 governs 271:19 grant 5:14 granted 44:4 great 14:21 22:8 38:19 62:3 64:20 128:13 206:22 213:3 232:11 247:11 264:10 265:8 274:5 312:14 greater 162:6 163:2	greenberg 3:20 gritty 84:11 gross 343:5 ground 260:10 group 64:16 71:6 72:21,21 80:24 82:18 94:5,10 95:14 98:19 133:6 139:2,10,16,16 146:16,19,20 147:19 255:18 266:4 268:4 269:10 271:14 272:19 274:7,25 275:5,7,17 276:5,6 276:7 278:19 282:7,20 293:10 293:21 296:22 297:10 308:20 311:5 grouped 274:19 groups 71:15 75:2 81:4 270:16 growing 161:3 guess 13:3 14:8 16:20 18:3 24:15 29:8,13 32:20 36:23 56:7 59:11 63:23 77:7 84:14 86:11 102:7 106:8 115:15 149:20 162:8 179:19 187:21 193:9 207:18 209:20 210:24 215:19 220:12 221:23 222:17 228:8 233:25 240:13,20 246:6 248:10,19 258:24 271:7 272:8,12 275:14	281:16 282:17 297:7 298:25 301:22 306:7 307:9 319:25 321:21 331:9 341:23 guessing 305:10 guy 150:21 h h 8:8 10:15 354:3 half 146:18 182:20 295:5 335:19,19 337:8,8 hand 314:8 349:10 352:15 handful 99:2 handle 119:21 157:20 178:12 290:22 312:12 handled 71:7 167:2 handling 121:4 313:10 hands 306:7 happen 97:13 107:20 140:22 141:6,21 165:7 273:5 301:5 311:16,20 happened 60:7 141:8 279:2 happening 160:11 happens 113:23 116:22 140:15 161:10 272:5 273:9 280:12 305:15 happy 12:5 41:23 196:4 232:5 271:21	hard 25:10 163:7 277:12 341:4,6 342:2 harder 348:5 349:14 harm 110:14 harmful 60:5,14 harmonize 37:21 170:15 harmonized 350:11 harmonizing 38:14 head 94:13 143:8 207:23 252:9 272:16 headers 19:15 health 88:4 98:24 114:17,22 203:17 221:2,4,7,9,12,13 221:16 223:12,17 223:18,21,24 224:4,15,19,21 225:24,25 226:3 227:4,5,11,16 229:3,11 230:2 231:17 243:5 245:6,8,9 250:8 277:16 287:14 294:21 healthcare 3:7 9:25 hear 17:25 147:18 150:10 174:25 heard 58:19 290:7 340:24 hearing 282:17 hello 17:5 help 44:25 116:15 131:19 152:14 154:5
---	---	---	---

[helpful - identify]

Page 28

helpful 38:16 59:4 117:15 254:8 helps 80:25 henry 5:8 hereinbefore 352:6 hereto 355:7 hereunto 352:14 herring 133:14 hesitate 298:14 hetero 47:25 207:25 338:9,19 341:18 hey 244:22 312:6 312:21 hi 322:18 hierarchical 274:13,20 hierarchy 274:8 275:11 high 158:3 higher 136:11 158:13 289:15 highlight 14:12 highlighted 45:6 highlighting 107:3 147:3 hill 7:12 hilton 2:9 hinshaw 6:20 hipaa 78:21 144:14 hire 132:6 311:21 311:25 hired 284:23 290:21 308:12 hires 286:7 287:9 hiring 289:16,18 historical 259:21 269:19 318:23	hit 26:8 349:22 hmm 129:20 hold 151:16 152:8 247:15 holder 149:24 269:21 holding 150:20 home 61:7 70:10 215:7 216:12 honik 116:17 117:3,8 honing 64:25 hope 14:10 38:4 138:19 174:10 hopefully 22:2 66:9 131:15 223:5 hopelessly 175:15 320:14 horrible 108:6 hour 20:23 61:21 100:24 101:6 108:18 182:21 231:23 295:5 349:23 hours 20:20 21:10 102:25 103:13 154:22 housekeeping 271:9 huahai 3:6,7 9:24 10:2 huge 161:22 252:4 hugely 260:3 huh 86:11 246:23 310:3 human 99:20 312:22 humana 19:2 27:2 27:4,14 hunchuck 4:16	hundreds 340:2 340:13 hydrochlorothia... 44:9,11 hypertensive 346:7 hypothetical 68:21 79:18 92:21 93:15 98:6 118:23 121:21 123:2 130:17 193:17 208:6,14 212:2 213:23 215:19 225:15 226:9 231:6 237:13 242:14 292:12 302:14 308:7 309:14 311:9 315:22 325:14 335:8 336:5,15 337:25 340:20 344:14 345:3 346:21 hypothetically 207:23	identified 40:8 41:4,5 50:19 57:10 60:22 70:8 72:13 78:15 95:7 105:2 111:19 126:4 138:8 169:22 170:25 245:17 249:17 252:5,6 255:18 297:17 318:7,11 319:9,18 341:16 identifier 171:22 334:12 identifiers 342:23 identifies 25:21 52:18 62:23 71:5 133:5 243:24 262:6,10 265:23 282:8 identify 33:23 35:6 45:25 50:5,9 50:13,22 52:10,13 53:8 63:5 64:10 71:17 77:16 87:23 88:9 89:14 91:19 91:22 93:6 97:25 112:12,16,25 113:21 121:9,12 137:16 146:24 147:10,22 148:4 150:2 172:22 177:23 178:3,23 188:14 191:10 192:18 194:24 195:7 196:20 198:7 203:15 216:20 218:21 223:7,12,19 229:8 239:16 243:5,10 252:16,20 253:3 255:5,8 257:15,19
		i	
		i.e. 83:7 223:19 285:19 303:16 idea 37:25 86:6 107:22 254:25 314:24 ideally 256:16 identifiable 74:9 117:20 250:19,23 identification 14:20 21:22 32:16 37:3 47:12 79:23 92:19 99:7 101:8 109:23 111:5 149:8 201:23 232:22 334:20,23	

[identify - individual]

Page 29

260:21 265:16,21 267:23,24 268:3 270:21 293:3 309:3 313:3 identifying 26:5 33:21 34:25 35:7 51:16 70:3,11 72:13 81:23 85:12 86:21 90:10 92:2 109:20 120:9 122:16 174:17 176:6,24 177:9 179:21 180:17 181:19,22 190:11 227:23 230:22 240:11 254:17 273:9 276:16 342:24 344:6 identities 176:8 311:6 316:17 identity 34:10 114:16 176:11 197:17 201:11 203:25 296:10,16 297:3 298:9 305:3 308:24 316:2 336:19 339:2 341:14 ids 36:2 265:24 266:3,4 344:2 ihs 257:11 iin 146:21 147:20 265:11 illogical 317:6 illustrate 161:19 illustrated 166:13 illustrating 161:21 illustration 236:10 255:12 illustrations 34:19	illustrative 34:2 imagination 311:18 imagine 331:25 immaterial 81:18 109:21 immaterially 276:3 immediately 273:5 273:10 impact 59:23 92:18 implement 209:15 implemented 148:21 238:9 implementing 184:14 implies 91:16 121:25 imply 316:12 important 11:23 24:25 34:4 61:9 83:13 111:24 283:25 303:6 imposed 124:16 impossible 131:4 156:9 288:10 impression 79:21 167:16 198:14 improper 46:6,7 200:8 improperly 46:3 improve 145:4 impurities 210:23 impurity 219:13 318:14 inaccurate 93:20 inactive 184:6 inappropriate 348:24	incentivized 316:16 include 20:21 35:9 35:10 36:11 74:8 113:24,25 123:7 129:17 164:18 172:3,7 187:3,4,6 236:7 240:4 263:13 278:15 335:3 346:10 included 30:10 32:18 35:23 40:9 42:19 48:10 49:14 49:19 57:21 88:15 88:17 89:4 94:11 138:14 231:3 238:19 283:6,8 325:9 343:7 includes 12:17 35:8 36:14 80:17 83:15 140:17 196:23 282:9 including 13:10 26:25 69:23 112:13 114:16 142:3 144:12 157:9 215:4 229:13 257:20 332:21 inclusion 235:25 237:9 329:3 330:11 336:2 342:16 344:16 incoming 134:2 139:25 143:14 incomplete 68:21 79:18 92:21 93:15 94:6 98:6 118:23 121:21 123:2 193:17 208:6,14 212:2 213:23	215:19 226:9 231:6 237:13 242:14 259:22 292:12 302:14 308:7 309:14 311:9 315:22 325:14 336:5 337:25 340:20 345:3 346:21 incongruous 315:3 inconsistent 237:8 237:18 incorporates 31:14 incorrectly 57:3 increased 209:17 289:21 increases 335:17 incredibly 138:5 independent 104:10 162:23 independently 162:22 269:2 indian 250:8 indiana 5:23 indianapolis 5:23 indicate 196:25 197:2 266:23 267:15 269:25 indicated 199:24 243:16 indicates 105:15 indication 110:21 243:17 indications 72:20 indispensable 189:5 individual 34:12 35:14 53:8 57:17 57:23 63:5 78:14 99:20 113:2 115:7
---	---	--	---

[individual - interesting]

Page 30

115:7 116:6	inference 106:21	ingested 209:10	290:2,3,8 301:13
123:16 126:19,20	106:24	212:19,25 215:25	314:18 317:4,15
132:4 141:15,19	influences 99:25	ingredient 170:12	insure 75:6
143:9 149:2,16	inform 98:15	198:11 277:22,23	insured 71:19
165:9 172:22	information 13:18	ingredients 52:14	74:12 83:3 86:22
174:15 186:11	31:13 33:21 34:25	inherently 103:11	87:12,17 88:4,16
189:23 203:15	35:8 36:6 64:15	initial 30:11 46:20	89:3,15 93:6
204:24 205:24	64:21 67:24 70:3	72:10 73:9 87:25	97:25 98:21
210:2,2,14 215:2	70:12 74:8,9 80:5	88:12 256:3	114:15 148:12,20
218:25 219:19,21	80:17 87:5 90:16	initially 46:11	171:11,24 222:13
221:11 224:3,23	94:18,25 96:6,23	initiated 110:12	222:14 242:6,16
226:20 231:13	98:9 104:22 134:4	110:18 119:19	242:18 248:11
235:5 239:9 262:6	134:22,23 136:19	193:5	267:16,16 269:8
262:11 269:20	139:6 140:5,10,17	initiative 238:4	280:24 287:16,16
270:23 304:17	148:8 168:15	injury 59:15,23	288:22 289:8
318:24 328:10	171:20 174:17	60:6	293:4,16,16,17
332:10,15 334:4	176:6,24 178:4	inquire 259:2	294:24 302:6
334:12 335:3,25	180:12 185:7	inquiry 115:11	303:22 307:21
340:5,12 341:5	186:21,23 188:15	133:12 257:23	314:19 317:16
343:8 344:5	192:16,17 194:11	insofar 244:16	insureds 335:4
individual's	195:5 196:18	instability 150:22	insurer 81:2 83:2
141:17 334:13	200:19 207:5	instance 301:6	83:8,15 91:4
individually 78:4	208:16 211:20	305:19 311:3	244:3,24 288:12
186:6 337:7	218:2,7 227:17	instances 70:24	288:18,23 289:9
individuals 35:4	252:15 253:8	74:11 156:19	insurers 71:10
223:20 227:13	258:3,23 259:2	291:20 293:11	75:2 77:8 288:14
228:4 230:4	260:7 262:4	302:9 315:17,25	insuring 288:8,11
342:15	263:25 264:14	328:4	intake 279:10
indulge 73:6	267:5,19 269:14	instantaneously	intellectually
247:13	269:17,19 271:10	141:9,13 270:22	277:12
indulgence 295:22	271:20 273:9,15	instantly 134:3	intend 42:5 101:13
industry 55:24	273:17,19 279:6	142:2	195:11 252:14
62:24 63:13,21	282:9,10 283:6,10	institute 160:6,18	intended 146:24
64:16 67:22	283:22 294:2,21	instructions 231:8	147:22 261:22
113:11 127:11	307:7 334:17	insurance 72:6	295:23
141:8 143:21	342:24 343:14	89:10,10,14	interchangeably
144:2,7,9,11	344:7	226:17 235:19	281:9
149:14 158:23	infrastructure	238:24,25 259:3	interest 76:4 163:2
159:9 161:5	252:23	262:19 279:12	interested 352:12
167:19 190:21	ingersoll 5:4	281:7 285:20	interesting 173:9
238:23 253:9		288:3,3 289:5,6	

[intermediaries - know]

Page 31

intermediaries 25:24 75:12 133:13 155:19 313:5	investigate 34:6 60:19 111:12 259:18	issue 22:3 40:23 41:9 44:8 46:13 46:15 49:7 56:11 56:12 60:13 76:8 76:12 98:14 128:19 131:6,8 152:14 156:10 209:21,23 225:20 230:17,25 242:7 249:18 287:22 306:4	44:25 47:9 84:18 109:15
intermediary 71:2 71:7 97:4 132:15 148:22 285:8 286:7 289:17,22 289:25 291:18 296:9	investigated 60:7 investigating 33:18	issued 346:2 issues 26:2,9 56:19 91:15 92:16,23 131:18	k
intermediate 27:18 28:19 30:19	invoice 8:18 102:14 103:12 105:5 108:12	it'll 36:23 294:13 295:6	k 1:15 5:6 352:3 352:19
internet 150:22 151:20 152:14	invoices 101:15,18 102:6,18 304:23	item 189:5	kanner 2:4 353:2
interpret 34:16 231:12,12,15 305:12	involve 92:12 132:9 241:18	items 47:24 49:6 267:5	kapke 5:24
interpretable 145:2	involved 9:23 77:21 84:21 87:11 91:14 146:6 155:2 155:17 197:18 208:18 252:12 283:11 321:10	iterations 176:21	kara 5:24
interpretation 229:20	involves 170:16 242:6 310:24 324:16	j	kass 7:8
interpreted 330:25	involving 92:4 107:14 319:10 321:6	james 5:25	kathleen 6:24
interpreting 331:12	ip 113:16	january 102:14 352:15	keep 12:19 13:15 54:21 107:10,21 107:22 151:10 152:24 252:7 276:15
interrupt 264:12 267:10 339:21	iqvia 40:8,17 57:5 124:2,4,16 125:4 126:17,22 127:4 233:11 234:2 236:9 245:23 246:10 251:17 252:14 253:4 254:7,19 255:3,13 257:22	jason 5:17	keeping 38:10 120:3 335:11
interrupted 132:10	irrelevant 80:6 118:4 139:22 239:12 309:23	jeffrey 6:8	kelly 6:24
interrupting 147:13	irs 177:8,12	jersey 1:3 4:7 7:14	key 94:4
introduces 157:6	isolate 334:13	job 61:16	keying 176:22
intuitive 277:13		jointly 250:13	kickback 256:25
invariably 36:14 72:22 96:17 129:12 274:12 297:12		judge 98:18 108:4 230:12	kicked 21:24
inventory 186:9 189:24 190:2,9,14 191:4 192:6 279:14		judge's 93:20 94:13 98:14	killian 1:15 9:10 352:3,19
		judgment 230:19	kind 119:12 122:6 125:15 148:7 187:8 216:2 254:3 254:4,13 271:7 274:13 279:7 283:15 313:2
		judgments 178:16	kinds 131:11 137:10 143:19
		july 344:11	klings 3:13
		jump 110:24	knocking 227:24
		juncture 182:8	know 12:2 14:2 15:9 16:24 28:3 31:19 37:21 42:10 61:4 63:19 71:11 75:19 76:13 81:8 81:16 85:16 86:13 89:13 92:13 93:23
		justin 7:19 9:8 13:22 22:12 26:17	

[know - l]

Page 32

93:25,25 96:19	knowledge 124:17	62:1 63:1 64:1	185:1 186:1 187:1
98:15,15 100:14	179:16	65:1 66:1 67:1	188:1 189:1 190:1
104:23 105:9	known 10:16,19	68:1 69:1 70:1	191:1 192:1 193:1
106:4 108:17	76:6 234:16 235:2	71:1 72:1 73:1	194:1 195:1 196:1
113:22 116:22	250:18 265:11	74:1 75:1 76:1	197:1 198:1 199:1
120:19,22 121:15	kosty 18:16 24:21	77:1 78:1 79:1	200:1 201:1 202:1
121:24 125:7	24:21 57:2 69:10	80:1 81:1 82:1	203:1 204:1 205:1
126:15 129:10	81:8 94:18 115:14	83:1 84:1 85:1	206:1 207:1 208:1
135:8,13 140:21	138:9 162:3 190:5	86:1 87:1 88:1	209:1 210:1 211:1
142:6,9,25 145:3	190:15 215:5	89:1 90:1 91:1	212:1 213:1 214:1
149:22 165:14	236:25 263:17	92:1 93:1 94:1	215:1 216:1 217:1
172:24 174:6,11	277:11 311:24	95:1 96:1 97:1	218:1 219:1 220:1
175:25 180:15	314:7 316:25	98:1 99:1 100:1	221:1 222:1 223:1
181:17 183:20	346:3	101:1 102:1 103:1	224:1 225:1 226:1
187:5 189:3,16	kosty's 18:15 21:9	104:1 105:1 106:1	227:1 228:1 229:1
192:2 193:12,13	23:8,12 24:14	107:1 108:1 109:1	230:1 231:1 232:1
196:10 200:5,6	131:16 250:17	110:1 111:1 112:1	233:1 234:1 235:1
207:24 212:12,18	265:20 313:4	113:1 114:1 115:1	236:1 237:1 238:1
212:24 213:2,4	317:7	116:1 117:1 118:1	239:1 240:1,10,10
222:18 223:21	kroger 28:4,9	119:1 120:1 121:1	241:1 242:1 243:1
226:5 233:25	35:10	122:1 123:1 124:1	244:1 245:1 246:1
237:20 245:10	kugler 108:4	125:1 126:1 127:1	247:1 248:1 249:1
246:16 247:16	l	128:1 129:1 130:1	250:1 251:1 252:1
249:15 259:15,17	l 8:5 9:17 10:1,14	131:1 132:1 133:1	253:1 254:1 255:1
260:6 265:9 271:2	11:1 12:1 13:1	134:1 135:1 136:1	256:1 257:1 258:1
273:14 279:18	14:1 15:1 16:1	137:1 138:1 139:1	259:1 260:1 261:1
281:14 283:9	17:1 18:1 19:1	140:1 141:1 142:1	262:1 263:1 264:1
287:11,13 290:6	20:1 21:1 22:1	143:1 144:1 145:1	265:1 266:1 267:1
293:6 294:8	23:1 24:1 25:1	146:1 147:1 148:1	268:1 269:1 270:1
300:13 302:10	26:1 27:1 28:1	149:1 150:1 151:1	271:1 272:1 273:1
303:10 304:7	29:1 30:1 31:1	152:1 153:1 154:1	274:1 275:1 276:1
306:8,23 308:2	32:1 33:1 34:1	155:1 156:1 157:1	277:1 278:1 279:1
313:14,22 314:10	35:1 36:1 37:1	158:1 159:1 160:1	280:1 281:1 282:1
315:8,18 316:7	38:1 39:1 40:1	161:1 162:1 163:1	283:1 284:1 285:1
319:19 320:22	41:1 42:1 43:1	164:1 165:1 166:1	286:1 287:1 288:1
336:13,17 339:24	44:1 45:1 46:1	167:1 168:1 169:1	289:1 290:1 291:1
340:7,14 347:18	47:1 48:1 49:1	170:1 171:1 172:1	292:1 293:1 294:1
348:2	50:1 51:1 52:1	173:1 174:1 175:1	295:1 296:1 297:1
knowing 314:16	53:1 54:1 55:1	176:1 177:1 178:1	298:1 299:1 300:1
325:18	56:1 57:1 58:1	179:1 180:1 181:1	301:1 302:1 303:1
	59:1 60:1 61:1	182:1 183:1 184:1	304:1 305:1 306:1

[l - linking]

Page 33

307:1 308:1 309:1 310:1 311:1 312:1 313:1 314:1 315:1 316:1 317:1 318:1 319:1 320:1 321:1 322:1 323:1 324:1 325:1 326:1 327:1 328:1 329:1 330:1 331:1 332:1 333:1 334:1 335:1 336:1 337:1 338:1 339:1 340:1 341:1 342:1 343:1 344:1 345:1 346:1 347:1 348:1 349:1 350:1 351:1 label 93:19 148:15 333:9 labeled 32:10 36:23 43:22 101:12 232:25 276:4 277:22 labeler 50:19 labeler's 50:18 labeling 61:12 185:6 labs 47:25 207:25 lacks 197:21 199:4 199:15 200:23 210:7 213:24 301:2 302:16 309:13 311:10 345:4 laid 67:14 68:25 97:20 language 66:24 87:21 89:2 244:4 265:20 270:6 275:23,24 laptop 17:9,12 large 69:12 83:2 99:14 145:3	163:12 170:2 212:13 245:16 299:12,16 317:4 largely 164:2 287:11 larger 265:20 largest 71:10 157:8 166:20 239:6 laura 1:8 8:11,15 9:5 10:14,19 352:4 353:5 354:2 354:24 355:2,4,12 law 7:5 64:23 184:13,15 185:22 law.com 353:2 lawyer 102:22 171:23 lawyering 107:6 lawyers 58:20 107:21 lay 24:23 layering 313:5 layne 2:9 layouts 19:17 laypeople 246:6 laypersons 246:7 lct 206:19,24 335:12 344:17 learned 11:13 leave 49:24 77:7 84:19 273:3 leaves 224:9,16 left 75:8 79:21 147:4 190:25 202:23 236:11,17 236:18 238:4 leg 252:4 legal 34:9 45:11 55:17 58:13,22 62:24 63:13,21	93:9 98:7 107:7 121:23 273:14 306:22 323:18 353:23 legally 42:10 122:2 144:14 legislative 244:19 legislature 257:22 length 256:18 329:4,12 lengths 335:21 leon 7:6 lest 84:16 letter 21:19 37:16 38:8 lettered 38:3 lettering 38:2 letters 38:11 266:8 350:10 level 125:16 126:5 126:8,18 138:10 212:24 213:4 219:21 244:7 260:9 302:19,21 302:21 318:12 340:12 348:23 levels 176:10 192:7 210:13 213:7,9 239:4 leverage 190:10 levin 2:14 lewis 4:12 liability 1:6 liable 296:11 liberty 169:8 license 11:18 125:5,8 licensed 11:15 lieu 67:4 life 61:11 190:25	lifetime 206:14 207:21 208:11 209:8 318:13 331:18 likes 312:19 likewise 185:23 204:3 limit 42:18 97:11 160:7 350:4 limitation 216:10 limitations 124:17 limited 58:25 90:22 94:2 194:15 198:4 205:12 283:3 287:5 limiting 40:23 55:9 297:22 348:5 349:15 limits 25:18 line 43:3 47:24 49:6 146:14 247:23,25 256:24 354:4,7,10,13,16 354:19 lines 86:14 123:8 159:16 256:19 290:3,9 340:14 link 35:16 50:12 83:10 113:15 123:15 138:22,23 141:24 174:5 186:5 269:7 273:8 linked 80:24 82:18 120:23 134:3 138:16,17 140:2 207:14 263:25 336:12 344:2 347:16 linking 134:23 135:21 145:15 146:13 174:14
--	---	--	--

[linking - maintain]

Page 34

298:21 links 133:6 140:9 221:11,13 282:6 list 8:16 22:11,14 22:18,19 26:23 31:9,10 45:24 47:17 65:17,23 66:4,15 68:8 71:15 75:2 85:19 161:6,7,13 179:5 179:23 180:10 181:5,11 218:3,12 220:14 221:15,16 222:19,22,23 223:17 224:11,13 224:22 226:19 227:12,21 230:4,5 233:4,10,14,18,23 234:3,5 235:25 238:12 245:25 248:8,21 255:22 257:23 258:10,15 263:10,11 266:15 276:20 277:7 320:7,19 321:4,9 listed 23:3 43:14 64:12 70:25 71:16 197:9,17 listening 13:16 321:17 lists 84:20 179:13 180:3,5,16 181:2 181:18,24 literal 338:5 literally 74:25 98:17 99:2 145:6 147:9 151:4 279:13 294:9 338:11 literature 214:23 345:18	litigation 1:6 9:7 49:7 65:11 69:16 78:14 86:15 91:17 96:19 100:16 124:18 170:3 178:14 212:13 213:3 321:2 327:22 334:18 litigations 178:15 little 50:2 84:10 95:5 97:16 100:10 135:19 136:11,13 142:22 146:9 158:22 168:6 229:20 271:2 280:6 313:6 322:8 330:5 332:6 333:25,25 liza 4:8 llc 2:4 3:7 5:5 llp 2:14 3:4,20 4:12,19 5:12,20 6:4,12,20 7:4 loathe 98:13 local 300:13 location 176:23 locations 127:7 locks 138:12 269:15 log 22:5 247:20 long 20:17 25:7 64:18 172:10 173:12 174:11 175:4,6,22 176:4 185:3 195:12 218:19 323:10 longer 12:16 110:13 182:15 295:23 look 14:9,14,14 15:8 28:6 47:22	49:13 51:6 55:4 60:25 64:13 73:7 125:9 132:16 133:2 136:11 145:12 151:22 158:15 192:6 201:25 215:11 251:22 258:21 259:5 279:25 291:12 292:3,4,15 292:16 299:16 302:20 306:20 333:19 338:6,12 338:13,15 339:8 339:18 349:18 looked 18:16 23:15 34:17,23 36:5 40:3 186:22 245:18 looking 17:22 18:7 21:5 28:25 51:3 80:11 102:19 104:10 131:13 137:25 171:23 173:19 174:20 189:14,15 219:9 242:4 249:20 271:25 279:19 280:19 299:12 330:9 335:10 340:5 346:6 looks 16:21 37:11 47:20 102:23 142:9 207:9 loop 107:21 loose 131:14 losartan 353:4 354:1 355:1 loss 59:14 210:19 210:21 319:10,18 319:20,21,24	323:24 losses 239:17 lost 147:8 211:6 306:17 lot 11:22 26:8 101:14 114:6 135:7,15 178:21 184:25 185:7,18 185:25 186:5,7,14 186:22 187:3,6,9 187:11,13,15,22 187:23 188:3,6,14 188:20,21 189:3,5 189:9 193:10,12 194:8,11,12,24,24 211:13,20 283:21 303:8 314:3 lots 80:4,4 96:10 99:22,23 113:25 135:5 137:23 193:6,11 194:16 209:25 211:2,18 213:16 214:7 249:11,11 louisiana 2:7 312:9,11,12,16,18 low 190:3 lunch 182:11
m			
m 5:17 201:19 240:10,10 329:16 ma'am 58:5 mada 19:23 20:3 magistrate 230:12 mail 100:8 127:15 164:19 main 14:8 maintain 114:13 185:25 271:4 272:13			

maintained 119:18 134:4,23 138:16 maintains 140:11 major 274:21 290:14 majority 51:15,22 52:4 186:20 187:3 187:5 maker 50:13 making 208:2 219:22 260:2 manage 289:18 managed 196:4 234:22 235:11,17 235:20 236:2,11 236:18 237:7,9 238:5 245:15 253:15 294:23 management 119:25 manager 130:12 managers 129:5 managing 178:20 mandated 144:14 mania 162:3 manipulate 34:16 247:21 manner 150:9,14 manufactured 40:19 43:22 46:3 48:2,23 110:11 187:18 188:8 332:11 manufacturer 50:5,9,16,22 51:5 51:8,17 52:10,13 113:15 119:18,23 183:16,17 185:4 190:18 204:6,16 329:5 336:17,18	336:23 339:3 341:9,11,14 manufacturer's 193:10 manufacturers 156:13 187:17 193:5,20 331:16 332:8 manufacturing 46:6 march 344:11 mark 21:18,20 32:10 36:24 47:9 201:20 233:2 349:23 marked 14:19 21:21 32:15 37:2 47:11 101:7 201:22 232:21 329:15,21 market 161:22 164:5 256:21 316:19 marketed 43:23 marking 268:19 marriage 352:11 mass 340:4 massachusetts 6:23 massive 339:25 master 121:2 199:23 200:11 match 103:2 175:7 176:7,17 191:22 252:14,19 343:2 matches 176:14,15 matching 139:24 176:11,21 224:13 material 26:13 41:10 120:20 225:8	materially 40:16 40:25 46:25 348:5 349:14 materials 8:12 21:10 22:14 23:4 23:9,13,14,15 26:23 31:4,10,12 31:16,22 32:2 42:25 236:24 math 102:20,22 103:15 matter 1:14 15:24 18:23 22:16 23:6 38:23 43:22 44:6 86:4 104:25 146:14 177:13 241:10 302:23 331:13 352:13 mckesson 4:20 203:17 mdl 1:4 mean 14:17 17:23 27:5 37:9 57:8 67:18 80:14,16 97:11,12 104:14 107:10 124:22,23 128:11 129:10,11 129:11 134:9 135:13 137:12 138:21,24 141:6 145:21 149:9 163:8 164:11 173:8 181:14 184:8,10 185:21 186:7 188:7 189:22 194:16 205:2 226:24 227:7 228:7,9,13 229:21 231:13,15 238:6 242:23,24 249:10 256:13	263:4,13 267:10 269:13 274:9,11 274:12 275:9 280:6 291:17 296:15,17 304:13 308:16,17 315:7 315:17 319:23 321:3,4 329:13 330:16 331:10 336:10 338:4 341:20 meaning 67:10 293:19 meaningless 175:24 means 44:8 50:3 58:21 93:24 94:14 185:21 186:9 241:24 275:12 293:16,17 298:20 meant 112:7 129:14 measure 323:17 324:6 325:2,5,18 measures 323:23 325:24 measuring 164:6 meat 129:2 mechanism 61:13 319:2 mechanisms 64:10 191:4 media 9:4 62:6,11 109:6,11 182:24 183:5 232:14,19 295:19 medicaid 135:10 234:7,9,15,17,20 234:22 236:7,8,12 236:18,19 237:6,9 237:21 245:14,15
---	--	---	--

[medicaid - minor]

Page 36

249:7 250:2,22 253:20 287:12 294:23 medical 8:20 57:18,22 59:14 173:19,25 174:24 175:5,10,19 176:3 205:19 217:2 318:7,8,11,20 319:3 328:7 329:3 330:12 340:9 342:17 344:16 349:4,12 medicare 135:10 234:6 235:14 236:19 237:7 238:13,20 240:4 253:20 287:12 294:22 medication 16:12 112:19 113:3,4,7 185:16,19 187:24 193:12 214:18 219:12 344:20 346:17 349:5 medications 185:2 348:15 meet 10:10 20:14 53:9 63:6 72:4 88:11 177:19 219:2 332:23 342:16 meets 335:25 member 35:13 36:2,12 89:9,11 121:10 122:18 128:6 139:2 155:3 172:23 177:23 218:25 221:13 325:7 332:10,15 335:9 338:7 344:2	344:19 members 26:5 33:23 57:10 59:13 64:11 65:17 66:16 77:16 85:12,19 88:7 89:5,6 90:10 92:19 109:20 122:16 178:18,20 179:22 180:11 181:23 188:14 190:12 214:17 216:21 217:2 218:4 221:25 227:21 230:6,13 234:10 251:18 253:3 254:18 255:8,14 276:17 276:20 318:7,11 318:24 319:9 320:8,10 323:22 325:25 328:10 331:15,22 349:13 membership 88:2 204:20 209:16 memory 18:18 mention 141:3 mentioned 23:7 65:8 82:15 96:12 142:17 190:13 193:2 213:11 250:2,3 278:2 286:15 305:14 309:19 merchantable 43:25 mere 163:6 merely 34:18 50:20 76:12,19 79:23 80:8 96:18 106:25 137:25 175:20 180:11	186:9 193:25 208:21 219:22 222:18 249:21 251:19 297:4 308:22 merge 25:17 172:10 173:15 174:12,18 175:4 277:9 merged 27:19 157:10 162:10,24 169:13,14 merger 162:3 merging 163:2 172:18 173:5 175:22 meridian 5:22 message 134:3 138:13,14 139:5 146:18 152:3 264:23 271:22 272:2,6,9 282:18 283:7 messages 142:10 144:13 283:16 messaging 138:3 139:21 140:6 271:18 mestre 7:4 met 20:12 21:12 88:5 334:4 337:13 method 123:4 180:10 196:24 197:5 253:19 methodologies 326:11 methodology 90:8 90:11 91:25 92:2 109:24 111:5 120:6 122:15 127:5 146:12	160:16 175:9 179:21 180:14 190:11 222:21 226:2 230:21 254:17 320:6 337:17,19 342:14 347:5 methods 213:5 253:18 metric 207:16 metrics 100:12 158:23 159:21 160:3 164:13,16 miami 3:23 middle 53:3 114:12 284:4 285:9 middleman 316:19 miles 17:2 milligram 207:25 335:16 338:17 339:20 341:17 milligrams 208:9 208:25 335:18 338:7,13,15 milliman 240:10 240:14,23 241:15 242:9 243:16,21 257:20 million 301:25 302:4 mind 13:15 66:12 108:21 150:19 155:9 232:6 252:8 335:11 340:25 mine 182:19 320:2 minimum 40:4 328:25 331:18 minor 276:12
---	---	---	---

[minute - names]

Page 37

minute 46:11 61:22 100:23 182:10 232:7 258:8 minutes 45:19 108:22 151:13 154:3,18 322:2,21 misbranded 60:4 60:14 mischaracterizes 175:13 202:15 223:2 291:5 292:10 misheard 236:16 mislabeled 60:4 60:13 misleading 293:22 misleadingly 115:13 missed 266:21 missing 94:4 99:24 170:22 280:12 misstatement 57:6 misstates 64:6 74:19 82:8 88:23 111:9 118:22 122:23 144:4 150:6 180:21 193:16 199:16 201:3 203:21 212:3 216:23 237:14 248:25 282:24 285:3,4 286:25 299:9 323:5 329:9 333:3 333:4 343:21 348:20 misstating 200:15 misunderstand 343:17,23	mix 132:9 mixed 191:15 mm 129:20 model 235:17 246:5,8,9,14,17,21 246:25 253:13,14 253:17,22,23 modification 315:13 modified 27:12 modify 241:24 moment 23:7 52:17 55:4 73:6 137:25 168:3 271:11 301:11 347:14 monetary 320:4 money 72:14 120:3 121:13 134:17 195:22 235:13 314:10 321:11 moniker 99:16 monitoring 8:21 57:19,23 59:14 173:19,25 174:25 175:5,10,20 176:3 205:20 217:3 318:8,9,12,20 319:3 328:7 329:3 330:12 340:9 342:17 344:16 349:4,13 month 125:22 126:4,12 176:9 304:17,19 305:15 330:24 339:5,10 339:11 monthly 125:16 127:8 342:5	months 207:24 208:9 330:15,16 330:17,18,23 331:4,5,6,7 335:14 335:15,18 336:14 336:24 338:8,9,10 338:16,18,20 339:4,16,19 341:17,18,21,23 morgan 4:12 morning 128:20 193:23 253:2 264:2 290:7 309:19 morris 3:4 225:17 225:19 morris's 225:24 motion 106:11 motions 105:17,20 105:23 106:3,4,5 106:20 107:2 108:4,11 mouth 20:13 move 26:12 84:9 84:12 127:16 156:25 195:2 220:2 267:21 moved 297:4 moving 244:21 msp 7:5 19:20 20:2,3,3 335:2 multi 25:11,16 multiple 25:5,18 67:2,8 114:12 174:3 192:5 201:5 248:15 249:15,16 265:24 276:18 277:2,10 278:5 313:21 332:21 multisource 170:7	murtha 7:15 mute 71:13 mylan 5:13 48:2 48:22 335:19 338:10,20
			n
			n 2:2 3:2 4:2 5:2 6:2 7:2 8:2 240:10 n.w. 3:9 nailed 211:14 name 9:8,21 10:13 35:22,22 57:10 75:7 76:17 138:11 139:8,15 142:19 142:22 149:9,10 170:11,16 176:18 176:21 195:23 224:12 243:12 257:10,12 263:12 263:23,24 266:15 272:18,19,19 275:25 276:2,2 278:18,19 286:12 288:25 290:24 291:13 293:6,21 296:12,20,21,22 296:23 298:19,23 299:3,24 300:4,6,9 301:14,15,20 302:8 303:12 304:11 307:4 308:18 317:5 322:18 333:9 334:11,20 named 20:2 37:16 55:22 56:23 69:20 69:21 296:25 297:2 names 10:17 19:16 33:22 36:5,17,18 70:10 142:25

[names - notes]

Page 38

163:14 179:23 221:15 273:14 279:23 297:18 308:17 316:13 334:23 335:3 naming 276:12 279:18 narrative 39:7,22 42:7 298:22 narrow 26:2 85:15 85:17 99:10 narrowly 349:12 nation's 163:25 166:3 national 45:16,25 241:16 nature 76:10 115:20 133:12 213:13 nepdp 95:12 134:22,22 135:20 136:15 140:6,9 142:11 143:15 144:9,10 260:17 261:10 264:8 271:12,15,18 272:10 282:18 ndc 8:16 40:9 49:13,14,25 50:4 50:11,12 51:3 52:9,12,17 55:15 61:10 91:21 111:16,21 112:11 112:24,25 113:4,8 113:8,18,20,24 114:7 125:21 126:3,13 187:14 187:17,24 188:9 188:19 192:12 205:25 209:21,21 209:23 210:3	211:3 213:8,16 214:8 217:12 218:2 334:9 336:20 341:13 ndcs 40:18 41:23 42:15,18 45:17 46:12 47:17 48:9 48:9 49:5 61:7,15 111:21 112:5,15 113:6 127:8 165:18 187:9,11 193:24 194:4 207:14 332:21,22 334:5 ndea 111:4 209:9 209:25 210:23 211:18,23 213:15 213:17 ndma 111:4 209:9 209:24 210:23 211:18,22 212:11 213:15,17 near 16:23 112:10 303:5 necessarily 38:4 50:4,8 52:10,12 128:16 156:6 181:14 189:10 260:25 283:22 316:13 317:5 327:20 346:10 necessary 42:12 66:7,14,24 67:7 68:2 70:23 75:15 76:20 79:3 91:3 122:2,12 123:6,9 123:14 173:12 257:9,23 320:19 320:21 321:14 342:11 343:14 345:22 355:6	need 12:21 14:13 14:14 51:6 54:25 55:3 65:22 66:10 76:13 77:3 79:22 79:25 81:14 89:13 89:20 133:2,12 135:8,10 138:11 140:14 151:24 153:7,8 173:7,14 173:15 174:2,13 176:2 179:24 180:16,24 181:6,7 182:17 190:4 193:11 194:11 200:19 202:11 203:9 208:23 211:19 212:10,22 224:11,13 231:7 231:19 232:7 252:13,23 254:24 258:6 260:11,20 264:13 268:14 270:20 273:3 275:12 277:17 280:2 283:9 284:9 308:2 314:20 316:13 333:19 334:3,5,8,11 336:16,18 needed 170:23 171:2 188:15,22 202:18 needs 65:10 71:13 87:22 141:13 151:21 190:25 238:7 252:19 265:16 305:24 338:7 349:18 neither 23:21 24:24 85:24	net 114:22 118:10 260:23 never 25:12 81:11 88:5 251:16,25 277:24 294:20 306:8,19 317:14 317:18,19 318:19 320:17 321:11,13 new 1:3 2:7 4:7 6:15,15 7:14 69:16 145:7 170:5 178:10 newark 4:7 niaspan 86:14,14 90:4,9,21 91:24 93:4 94:23 97:24 nice 10:10 173:9 nicely 91:20 162:2 nilly 285:15 nine 109:18 112:8 163:23 166:11,24 172:11 nitpicking 66:23 nitrosamine 61:2 110:16 nitty 84:11 non 25:9,9 43:25 48:23 49:4 nope 116:2 normally 288:14 norton 4:19 notary 1:17 355:13,19 note 10:4 45:23 53:23 56:22 177:5 179:8 196:22 247:25 353:10 noted 9:12 199:20 351:11 355:7 notes 1:13 15:25 73:7 295:8
--	---	---	---

[notice - objections]

Page 39

notice 8:10 14:25 15:19 178:19 197:12 notices 180:3 181:2 notify 13:11 noting 106:19 novel 254:5 november 16:8 38:24 number 9:22 11:2 36:14 38:3,9 40:16 41:23 47:23 51:21 52:6 55:11 69:11 77:7 80:25 82:19,25 84:20 94:5,10 95:14,14 115:6 126:11 139:4,9,15,16 146:21,22 147:20 147:20 159:22,25 164:7 165:5,14,15 167:14 184:12,25 185:18 186:2,5,15 186:22 187:3,6,13 188:15,20 189:4,5 193:12 194:16,24 204:20 208:25 211:13 218:12 220:19,23 224:7 231:12 243:12 247:15 252:12,21 265:11,25 266:3 267:18,20,22 268:16,17,22 269:3 275:9 278:14 297:15 298:21 309:17,18 334:9,20 336:13 336:14 338:24 339:19 342:5	numbered 26:16 numbers 29:14 33:17 34:2 35:11 35:12 38:12 40:21 40:24 103:10 123:11 133:13 137:14 138:18 158:10 159:14 160:25 186:8 187:10,12 188:22 189:9 208:3,8,10 225:8 266:8 267:2 269:5 270:20 272:20 287:4 298:16 301:19 303:4 334:5,23 350:11 numeric 147:5 261:18 262:15 266:7 numerosity 41:9 46:21 47:5 48:12 49:15,19 53:25 54:7 55:10 56:4 56:13,25 58:7 124:15 233:19 236:11 237:10,19 253:6 322:25 323:8,15 340:25 numerous 71:12 161:7 219:23 233:16 251:20,25 nuptials 196:7 nw 5:6 o o'reilly 4:4 oath 352:5 objecting 117:6,8 objection 15:17 17:20 19:12 24:7 32:6 33:13 36:8	41:17 43:7 44:12 45:7 46:17 49:8 50:6 51:10,24 53:17 54:9,17,22 56:14 58:12 59:16 60:17 64:2 65:18 68:12,17 73:14 74:17 77:17 79:5 79:13 82:4,21 85:8 87:3 88:19 90:13 92:6,20 93:11 95:17 96:9 98:3 100:5 101:2 103:5 108:13 109:25 111:7 112:20 114:3,24 115:22 118:20 120:11 121:17 122:20 124:20,24 129:7 130:15 132:20 134:12 135:3 136:2,25 140:12,23 143:3 144:3 145:17 150:4 155:7,20 156:4 157:21 162:13,16 164:14 164:23 167:4 168:12 169:16 171:17 172:14 175:11 177:25 180:18 181:8,21 183:18 186:24 187:25 188:16,25 192:21 193:15 194:13 195:24 197:19 198:25 199:11,21,22 202:9,13,22 203:19 204:10 205:8 206:25	208:4,13 209:11 210:5 211:5,24 213:20 214:19 215:17 216:22 217:13,19 222:5 222:24 226:7 228:20 230:7 231:4 237:11 239:21,24 240:16 241:4,20 242:12 243:22 248:13,23 250:6,15 251:3,10 252:17 254:20 255:15 256:6 259:9 266:17 269:11 270:12 275:2,20 276:21 281:25 282:22 284:13,24 286:22 291:2 292:7 298:11 299:5,18 300:23 302:12 308:4 309:10 311:7 313:18 315:10,20 316:22 318:15 319:12 320:12 323:3,25 324:11 325:11 326:3,17,23 327:7 327:23 328:13 329:7 331:20,24 332:25 336:3 337:22,23 340:18 342:18 343:19 344:23 345:2 346:19 348:18 objections 15:14 15:18 54:22 91:11 104:6 119:9 198:16 200:23 292:22 310:2
---	---	---	---

[objective - opine]

Page 40

objective 67:21 173:5	occasion 81:21,24 127:25	49:3,12,22 50:24 52:7 54:4,14 58:5	272:7,15 273:22 274:3,4 275:14
objectively 306:9 307:8	occasionally 107:20	59:9 60:9 61:19 62:20 65:13,20	281:11 282:13 284:19 287:3
objectives 172:20	occur 130:25	66:21 71:14 73:22	291:23,24 295:10
obligated 239:13	131:4 140:21	77:5 78:7 79:4	297:6 298:5,24
obligation 34:9 238:18	141:11,12,22 143:7	82:14 84:8 85:20 86:8 90:2 91:7	300:3,15 309:5 310:12 322:3
obliged 13:11	occurred 110:17	95:20,23 97:14	327:18 328:19
obligor 256:15	344:10,18 347:24	100:17,21 101:9	330:3 331:2
obscure 296:10,16	occurs 130:24	101:23 102:10,16	333:23 335:6
obscured 297:2	131:3	103:22 108:24,25	341:9 342:8 344:8
observable 208:23	ocean 99:17	113:19 116:13	350:15
observation 125:24	offered 90:9 326:22	117:4 119:8	old 260:10 285:20
observations 342:6	offering 45:3 46:5 54:5,11 56:5 58:8	123:17 128:13,24 140:19 142:16,24	omnipresent 61:12
observed 127:4 144:14 276:13	59:12 63:24 313:16 323:16	143:23 147:15 151:6 154:15	once 70:21 74:10 75:10 98:13 100:9
obtain 53:21 77:15 94:24 99:21	324:8,19 325:4	169:3 172:8 175:18 178:25	176:6 224:25 229:16
118:19 179:22	office 16:21 24:10	179:11,11 184:4	onces 291:10
181:7 242:9	116:23 258:22,25	194:25,25 195:20	ones 11:23 48:14
252:15 273:4	259:23 312:23	199:9 206:8,20	91:9 143:2 160:25
obtained 65:5,8,15 77:11,14 79:9	offset 123:10	208:3 209:4	ongoing 163:3
125:13 126:16	oh 116:13 196:8 311:25	210:17 211:4	online 258:21 259:21
168:4,9 184:11	ohio 6:7	220:4 221:22	open 17:12
189:9 200:3,12	okay 10:20 11:8 11:20 12:12 13:8	222:4 224:10	operate 215:7
204:5 211:21	16:5,10 17:5,16	225:14 228:17	operated 257:3
230:3 240:23	18:11,25 19:18,25	229:15,23 232:2	operates 83:2,4
241:2	21:3 22:8,9,23	233:17,21 234:12	operating 130:6 161:7 215:23
obtaining 69:14 74:2	23:11,18,23 24:3 24:13 26:6 28:22	234:20,20 235:8	operation 179:5 317:2
obvious 117:9	29:7 30:13,13,23	236:18,21 237:3	operations 145:10 220:24,24
obviously 37:18 64:11 102:11	31:25 32:8,25	240:20 242:20	operative 184:7,9 184:11
110:14 146:2	33:4,7 34:21 36:3	246:13,20,24	opine 59:8 121:6 214:12
176:22 223:12	36:20 38:20 39:9	247:5 248:6,18	
250:12 264:14	39:18 41:11 42:20	249:23 250:20	
272:2 307:16	43:16,19 45:22	260:13 261:5,21	
	47:6,21 48:7,19	262:2,7 264:3,5,6	
		264:10 265:14	
		266:5,10,19 267:9	
		267:13 270:8	

[opining - paragraph]

Page 41

opining 45:10 66:6 opinion 25:19 31:15 33:12 43:6 45:4 46:6 53:24 55:14,15,18,21,25 56:3,12,22 57:20 58:14 59:12 60:23 76:19 85:6,11,15 86:2,20 94:23 99:9 118:3 120:21 124:15 173:17 177:13 210:13 214:6 223:3 233:19 238:11 239:12 297:2 323:16,21 324:5,7 324:8,15,20,23 325:4,8,21 opinions 22:16,20 24:15,18 53:21,23 54:5,11,18 55:6,9 55:12 56:4,10 58:9,18,22,25 59:3 63:24 86:10 107:9 108:2,3,8 111:9 124:12 193:16 237:14 322:24 323:12 324:21 333:5 opportunity 131:16 277:4 opposed 28:12 41:2,5 51:8 79:23 128:14 159:19 163:3 193:11 204:24 207:16 opposing 15:22 327:17 options 338:22 optum 163:9,11	optumrx 6:13 order 13:14,17,20 54:23 65:16,23 78:21 87:7 90:17 93:20 98:10 100:8 121:9,12 127:15 141:25 144:18 164:19 167:7 197:25 198:15 214:7 216:20 218:8,11 251:19 259:11 265:10 273:4 277:6 279:7 287:4 316:14 ordered 78:20 orders 105:17 106:2,6,8,11 107:2 241:7 319:16 ordinarily 122:7 organization 144:11 162:4 234:24 235:12 organizations 236:2 237:10 organized 138:6 322:7 oriented 216:7 original 28:7,8 35:13 originally 178:7 orleans 2:7 outcome 42:18 225:3 352:13 outcomes 143:19 outdated 190:24 outgoing 143:14 outliers 289:7 outline 261:9 outlined 180:6 181:3	outlining 180:7 outlook 214:11 output 30:15,17 outputs 30:4,6 145:12,12 outreaches 260:3 outside 21:13 64:22,23 210:9 212:7 324:3 325:13 overall 157:20 275:10 overarching 53:19 overcharge 319:21 overlap 347:22 overseen 73:13 owned 288:16 oxford 4:14 5:15 <p style="text-align: center;">p</p> p 2:2,2 3:2,2 4:2,2 5:2,2 6:2,2 7:2,2 128:15 p.c. 5:4 p.m. 351:11 pacific 109:3 package 27:23 173:11 267:25 268:6,14,15 275:8 packaged 43:23 packages 81:16 268:3 327:12,14 packet 8:18 page 8:4,9 15:4 22:11 26:16,16,20 29:3 32:13 39:3 42:21,22 43:18 44:17,18,21,21,23 47:22 48:15,17,20 52:21,25 55:7 62:14 100:18,19 101:19,21 105:3	109:16 114:9 123:24 127:17 128:4,10 133:22 136:11 156:25 163:19 183:8 184:2 195:2 196:15 201:21 202:8,24 205:16 220:3 240:8 241:13 245:22 258:4,18 261:6,8 270:25 295:3 296:2 316:5 329:24 330:2,9,10 354:4,7,10,13,16 354:19 pages 26:22,24 45:14 paid 34:12 75:20 75:21 89:12 91:20 100:24 101:4,4,5 103:24 111:3 114:18 115:9 118:5,11 120:2,7 120:20 121:13 122:9 123:15 134:25 135:6,14 135:15 173:4,22 201:12 230:24 234:7,16 242:2,5 323:22 324:17 325:25 paper 80:15 paragraph 42:24 45:14,15,23 52:24 53:13 57:14 62:14 62:22 84:16,17,20 100:19 109:16 112:6,8 114:8,12 123:25 124:5 127:17,22 131:13
--	--	--	---

[paragraph - pays]

Page 42

133:21 135:21 136:17 137:24 157:5 163:18,21 166:8 177:3,4,5 183:8 184:5 195:3 196:14,16 205:16 205:18 206:12 215:12 220:3,5 240:8 241:11 243:15 245:22 246:5 258:4,18 260:6,16,24 270:24 271:5 272:4 278:16 280:14,19 281:4 281:23 284:3,4 295:2 296:2,8 298:2 299:23 313:13 316:6 330:6,8,9 paragraphs 109:18 parallel 297:19 paraphrase 51:2 paraphrasing 307:12 parse 249:9,21 251:7 part 19:10 29:11 73:19 74:25 75:8 95:15 96:3 116:5 137:12 146:16 159:5 161:16 179:20 180:5 195:9,14 198:9 204:13,15 233:4 238:13,20 239:20 240:15 244:20 272:22 273:2,20 278:3 279:23 310:23 317:7	345:11 partial 38:25 participants 127:11 149:14 participate 181:13 349:3 participation 173:2 174:21 particular 36:4 65:10 71:6 84:23 96:24 98:16 110:25 111:14,16 111:21 119:15 127:7 148:5 167:18 172:25 174:8,23 185:5 187:16 189:6,8 190:3 191:12,25 192:8,13 203:24 207:17 213:8 229:3 244:2 249:19 253:18 255:17 268:5,20 275:13,19 283:14 288:20 301:16 303:3 308:18 331:15 338:25 particularly 78:16 90:25 99:12 294:3 342:2 parties 67:10 114:12 352:10 party 8:20 25:2,25 40:4 67:11 75:25 79:11 86:21 128:12 129:18 130:9 134:10 148:21 155:4 156:16 159:2 177:9 196:25 197:3,9 198:19,24	201:11 204:23 220:25 233:5,6 253:21 260:22,25 261:4 269:16 270:7,9 279:11 286:6,8 291:21 300:21 305:18,20 307:16,22 310:22 310:24 314:25 317:20 passage 44:6 passing 161:9 patient 114:17 195:7 patients 156:22 261:23 pay 88:6 126:9,17 134:17 158:17 195:21 205:3 215:8 222:12,12 239:14 264:20 287:8 312:14 314:16 payer 75:25 128:12 196:25 197:3,9 payers 25:2 156:17 159:2 paying 60:3 83:7 119:19 120:24 128:7 135:24 195:9,14,16 230:3 234:10 235:10,11 235:13 243:25 285:20 payment 59:21 69:5 72:8 88:3 94:17 116:6 117:25 196:21,24 197:5 253:18,19 265:17 277:21	286:3 314:5,14 320:4 payments 104:12 122:11 126:19 239:8,19 240:4 321:6 324:25 payor 57:10 67:11 71:3,8 79:23 80:11 88:10 89:8 96:23 128:14,15 128:21 133:9,25 134:8,9,14,19,24 149:10 173:3 179:4 198:24 201:11 220:7 239:13 243:8 250:7,15 254:4 256:15 269:15 270:2,2,3 276:2 279:11 280:21 284:5 286:6,16 290:17 292:6 302:21 303:9,13 303:16 304:17 305:7,18,21 307:16 310:22 313:24 314:2 316:2 payors 8:20 40:5,7 41:5 56:24 86:21 89:6,14,24 91:5,22 95:2 126:11,12 127:7 137:11 177:10 181:19 198:19 204:23 220:25 233:5,6 237:7 247:9 250:5 250:17,19,22 252:5,21 pays 224:20 235:12 268:7
--	---	---	--

[pbm - personal]

Page 43

pbm 25:23 69:14 70:21,24 72:14 74:2,10 75:4,18 77:12,14,22,23,23 79:7 83:25 84:4 93:5 94:2,8,9 95:11,11,21 96:3 96:11,13 97:5,18 97:19,24 99:5,13 99:16,23 100:3,7 100:11 116:4,7 120:23,25 128:21 129:22 130:3,14 130:19 133:7 134:11,16,17,25 135:25 136:21,22 137:11,16 138:3,5 138:16 139:5,9,24 140:11,21 141:25 142:5 143:13,20 143:22 144:21 145:4,5,16,20,23 147:9 148:3,10 149:4,5,11 160:3 161:17 162:11,25 163:12 164:5 170:19 171:4,9,10 171:15 173:15 174:17 175:8 214:15 217:9 218:3 223:20 243:10 246:17 249:17 252:15 255:5,23 257:11 260:19,21 261:23 263:22,23 264:5 264:16,23 265:4,5 265:22,23 266:2 267:5 268:17 269:5,14 271:22 272:2,2,6 276:11	276:25 277:10 279:13 280:23 281:13,17,20 282:5,12,12,16,20 283:2,7,18 284:22 285:10,13,22 286:3,10 288:20 289:11 290:22 291:11,15,18 292:3,24 293:2 294:14 296:12 299:12,16 300:9 300:18 301:7 304:2,5 305:4,17 305:24 306:4,19 306:20 307:12,13 308:12,23 311:2 312:24 313:11 314:6,24 315:5,8 315:14,17,25 316:12,18,18 317:12 328:18 343:10 pbm's 74:11 80:10 132:11 134:24 136:22 270:3,10 285:14 307:24 316:6 pbmi 131:17 pbms 69:2,12 71:4 72:19 74:12 78:5 78:22 79:10 80:18 94:16 96:19 99:17 100:14 129:6 131:15 132:6 134:5,24 140:16 143:9 144:17,22 146:5,8,15 155:4 155:18,24 157:8 157:17,20 158:11 159:3,6,15 161:3,4	161:6,7,9,10,11,13 161:21 162:8 166:10,20,24 168:11,22 169:13 170:11 172:11 174:12 176:8,8 254:10 256:11,18 257:6,15 270:21 271:4 272:13 274:7,21,24 275:16,25 276:6,7 276:15,18 277:2 277:14 281:10 288:15 293:24 313:14 314:15 320:25 pcn 139:4 267:22 267:23 268:8,14 271:14 pdf 15:5 101:24 201:21 330:2 peculiar 290:12 peer 345:18 pen 80:16 penalty 146:5 pending 12:23 pennsylvania 2:17 4:15 5:16 people 86:10 99:19 120:3 154:4 154:7 percent 158:8,19 158:20 303:15 305:7 percentage 157:16 165:20 166:25 176:15 perfect 14:21 25:12 176:10,14 176:15	perfectly 12:22 214:12 perform 82:13 132:6 141:25 144:18 149:6 327:21 342:12 343:15 performed 41:15 137:11 143:12,17 166:16,17 251:19 343:4 performing 145:10 343:12 performs 142:20 period 21:7 160:22 165:13 172:13 174:9 191:13,16 192:13 192:14 207:10 209:10 225:21 230:24 324:19 332:4 periodically 107:13 259:18 periods 25:7 27:19 102:7 161:15 191:22 212:15 231:14,16 279:16 331:16 333:18 perjury 146:6 permission 182:2 permitted 125:6 persisted 218:17 person 34:10 105:6 152:13 195:15,17 204:8 209:9 224:4 230:20,23 231:2 337:13 personal 34:25 35:6,7,17 70:2
---	---	---	---

[personal - plan]

Page 44

176:6 219:18 personally 15:11 33:21 74:9 145:25 176:24 259:25 344:6 personnel 220:10 220:21 221:24,24 222:20 223:19 227:3 229:22 257:24 259:5,23 persons 57:21 227:8 230:16 perspective 91:19 134:25 173:6 pertain 323:7 pertinent 111:4,11 111:15 pharma 4:13 170:4,5,6 179:3 pharmaceutical 3:5,6 9:24,25 52:11,14 62:23 63:12,20 64:16 67:22 69:16 113:11 127:11 146:4 154:25 167:2 178:14 179:18 190:21 195:6 196:19 253:9 254:6 289:13 318:14 319:11 pharmaceuticals 3:21 4:5 155:16 278:6 288:7 322:20 pharmacies 18:22 26:25 32:4 34:7 69:20 70:4 142:10 156:14 163:22,23 164:6 165:4	166:11,24 172:11 184:11,25 185:23 189:13,25 190:10 190:16 192:12 195:4 196:18 201:10 254:10,12 314:7 343:3 344:5 pharmacist 263:18 pharmacy 8:14 25:23 27:3,13 32:21 33:6,10,24 78:9,12 118:3 120:24,24 129:5 130:12 134:3 136:21 138:4,10 138:14 139:21 141:23 165:8,25 185:3,16,19 186:14,21 189:20 191:10,25 192:16 195:16 196:17 197:12,16 198:22 201:14 204:5,18 205:5 214:16 217:9 218:3 261:11 264:5,17 264:17 265:4,6 268:11 271:22,25 272:6,9 279:13 282:18 283:7,17 306:25 317:22,23 328:11,18 343:10 344:3 346:15 pharmacy's 35:17 35:25 phases 65:10 philadelphia 2:17 phone 17:15,22 58:3 259:4	phrase 35:7 95:10 114:11,20 118:10 167:11 physician 335:17 pick 113:2 116:19 117:12,19 195:20 picture 103:17 piece 80:15 321:2 pieces 283:6,10 pietrogallo 5:12 pii 74:8 78:8 pill 212:25 306:24 pills 210:2 331:8 pittsburgh 4:15 5:16 pizzi 4:4 place 13:17 75:22 75:23 88:11,15 142:15 173:16 174:2 180:12 191:4 278:6 312:23 placement 141:16 places 72:23 96:5 plain 70:14 plaintiff 2:5 19:9 20:6 55:22 340:15 351:4 plaintiff's 102:6 103:25 104:20 335:22 plaintiffs 2:15 10:23 16:20,22 18:19 19:6,10 20:2 21:14 43:21 46:2 53:4,14 60:20 237:5 323:19 329:2 335:12 340:9 344:17	plan 57:10 71:4,6 72:13,17 74:13 75:5,20 78:23 79:7,9,22 80:3,13 81:6 88:4,16 89:3 89:9 95:13 96:24 96:24 97:11 114:17 125:17,21 126:4 131:20 134:20,20 135:9 138:11 146:20 147:19 172:7 177:16 221:13,25 222:13,14 223:21 223:24 224:4,15 224:21 225:25,25 226:3,6 227:16 229:3 239:7 242:17,21 243:11 243:12,12,12 254:3 256:5 257:6 257:11 262:13,14 262:22,23,24,24 263:3,7,8,9,10,11 263:20,21,22,23 263:24,25 265:21 265:24 266:3,12 266:16,20,22 267:4,14,20,23 268:13,25 269:16 269:17 271:13 272:23 273:12,18 275:7 280:24 285:21 286:13 287:6,25 288:23 291:16 294:22,22 296:20,25 297:3 297:16 300:12 302:21 303:10,11 304:9,9,9,10,12 305:4 307:22
--	---	---	---

[plan - prescription]

Page 45

308:19,25 plan's 114:22 plane 280:7 planned 346:8 plans 40:7 41:2,5 56:23 71:15 75:2 86:23 87:12,17 89:5,16,21,23 92:14 93:6 97:3 97:25 99:8 158:16 171:11 221:2,4,7,9 221:12,17 223:12 223:17,18 227:4 227:23 228:4,6 229:11,13 233:5 235:24 236:5 238:14,20,21,22 238:23 239:5,20 240:5,11 243:5,5 243:11,17 244:7 245:6,9,11,19,25 248:15 249:9,15 249:16,21 250:4 250:23 251:7 252:6 253:12 255:18 256:12,14 256:20,22 257:2 257:14 259:3,19 270:17 277:16 287:21,24 288:6 290:13,15 293:25 303:8,12 312:7 platform 162:23 platforms 145:24 plausible 317:2 please 9:14 10:12 13:15 21:18 32:9 87:8 90:19 98:12 100:20 114:9 116:21 133:22 153:2,18,22	169:20 182:16 196:14 235:21 258:5 270:25 pleasure 136:9 plus 27:3 282:18 pocket 141:20 324:25 325:7 point 8:18 11:11 12:21 21:14 51:19 65:16 69:23 72:18 79:3 100:16 101:5 101:18 103:24 104:4,13,19 108:19 115:10,12 115:21 127:21 137:24 138:2 159:11 168:8 208:21 219:22 231:23 251:14 299:21 306:17 310:13 320:17 326:22 327:4,20 333:12 345:9 348:3,4 pointing 96:18 117:9 316:5 points 33:20 190:15 342:11 ponce 7:6 pops 138:12 populate 35:20 populated 139:13 139:23 294:16 population 177:19 239:7 303:25 poring 101:14 portable 144:24 portfolios 118:2 portion 39:7,23 42:6,7 52:24 81:22 105:5 144:9	193:25 198:5,9 201:14 205:15,18 229:4,5 234:6 portions 229:7,14 272:21 347:10 pose 93:7 225:11 225:14 position 93:19 220:17 possess 161:21 possession 348:9 possibility 128:20 167:25 216:11,13 244:14 333:15 343:24 possible 51:18 53:7 62:25 63:4 64:10 69:25 130:7 130:10,18 131:18 137:15 162:21 205:23 224:17 268:9 292:3 300:18 301:4 304:22 315:24 332:13 333:19 post 102:8 114:21 115:5,19 234:25 potential 155:3 230:6 319:15 323:22 325:25 349:19 potentially 60:4 60:14 255:6 257:21 332:20 ppo 263:15,19 practical 83:14 194:17 practice 293:20 344:13 practices 62:24 63:13,21 64:17,23	pre 101:12 194:4 232:25 preceding 206:4 precise 64:14 212:10,22,22 213:12 297:14 precisely 55:4 128:18 155:11 219:7 227:9 237:20 precision 213:4,9 predates 194:3 preeminent 241:16 preexisting 288:14 preface 315:11 prefer 154:14 prefers 154:11 prelabeled 47:8 premature 251:14 premise 65:24 155:23 156:11 premium 235:7 preparation 20:10 40:2 66:3 prepare 18:12 218:11 321:18 prepared 28:5 37:5 65:24 238:11 321:4 preparing 77:21 233:22 prescribed 346:11 347:3,4 prescribing 216:9 prescription 34:8 69:4,13 98:21 117:19 118:17 158:12 159:18 163:25 164:12 165:10 173:4,22
--	--	--	--

[prescription - produced]

Page 46

175:8 186:6,11 194:19 195:8,21 240:5 250:11 261:24 262:11 288:7 320:5 321:7 340:3 345:12 348:7 349:19 prescriptions 75:20,22 114:15 126:11 127:14 157:7,17,19 159:17,25 164:7 165:6,16 172:24 186:2 210:3 212:21 215:6 218:21 247:2 302:2,5,22,25 318:24 343:7 presence 111:13 296:8 present 7:18 87:12 170:21 171:21 176:25 185:24 282:10 333:8,22 334:16,24 presentation 28:14 presented 302:25 341:21 presently 231:9 presents 22:18 313:8 preserved 283:23 pressing 142:13 presumes 197:22 199:5,14 presuming 60:6 presumption 223:25 pretty 94:5 107:7 159:13 160:4	224:6 245:2 259:21 279:10 288:10 337:15 340:6 341:12 preview 26:7 previous 281:3 323:5 previously 141:17 303:18 price 34:13 75:24 75:25 118:10 122:5 142:3 158:18 198:9 235:18 264:15,22 264:22 282:7 primary 322:5 prime 191:17,19 192:16 princeton 7:14 principally 169:24 prinston 3:5 9:23 print 186:10 printed 272:22 298:19 prior 10:18 46:23 63:4 82:8 104:5 110:11,17 199:16 201:3 230:18 234:24 236:22 269:4 286:25 291:5 292:10 343:21 344:18 private 234:24 privilege 207:6 241:8 259:12 279:7 319:15 privileged 208:16 privy 316:2 probability 289:16,21	probably 11:2 26:9 51:25 73:5 174:16 176:16 182:14 244:9 probative 99:12 problem 38:13,13 41:21 66:24 106:16 202:20 224:10 227:6 247:19 257:8 287:11 290:12,14 problematic 333:21 procedural 44:6 procedurally 107:10 procedure 10:7 147:15 169:21 214:13,25 318:21 347:13 procedures 144:12 169:23 170:18,24 proceed 13:6 90:19 98:12 151:25,25 153:11 153:21 154:13 169:20 proceeding 32:12 38:15 process 11:10 31:19 57:12 69:12 69:23 71:21 73:9 73:12,19 78:6 82:12 97:13 112:13 120:18 138:22 140:20 141:7 142:14,18 145:15 146:6,10 155:2,17 170:16 181:3 190:5 208:19 226:18	227:15 245:5 254:3 273:2 278:7 320:21 321:12 processed 157:7 157:18 159:16,23 161:2 223:22 225:3 263:2 303:2 processes 61:3 176:21 178:19 180:5 processing 27:16 27:22 169:25 170:9 224:21 265:17 268:18 269:6 278:4 286:10 287:17 349:2 processor 95:13 146:21 147:20 267:21 268:16 procurement 131:25 produce 19:4 28:19 31:16,24 65:16 71:4 72:19 74:13 78:19 96:21 140:16 198:6,11 276:19 320:7 334:22 produced 15:13 18:19 19:23 20:4 27:8 28:11 29:6 29:10,25 30:20 33:10 36:16 39:13 65:3,10 67:19 74:8 78:3 80:21 81:7 90:23,24 101:18 163:16 164:3 165:25 186:17 197:13,16 197:23 198:12,23
---	--	---	---

[produced - pull]

Page 47

199:8 201:9,15,17 207:25 211:2 283:24 299:20 320:25 334:18 342:25 producing 33:9 41:16 227:21 product 31:11,15 31:23 40:20 45:11 50:9,14,23 55:20 61:11 110:6,10,13 110:21 111:16 112:12,16,17,23 112:24,25 113:10 113:12,15 114:2 119:4,14 122:9 125:21 148:5,6 156:14,15,16,21 156:23 167:3 173:23 174:6,22 179:15 181:16 185:10 188:8 189:9 190:3,22,24 191:17,24 192:7 192:11 193:20 194:12,18 195:17 195:18 204:17,18 205:4,13 207:15 208:25 215:25 217:11 218:4,16 218:18,23 242:4 264:19 282:8 330:16,20 331:4 331:16 335:16 336:14 342:6 347:3,19 production 15:22 19:11 20:6 163:10 163:11 167:10 169:5,22 171:3 198:5 233:4	279:20,21 productions 19:6 70:5 77:24 78:9 176:9 277:5 products 1:6 46:2 61:5,17 91:21 110:15 111:14,18 112:4 113:11 126:10 158:9,19 165:10 167:18 191:12 194:2 209:3 210:14 212:16 219:4 235:18 279:16 287:15 319:11 324:18 332:3 333:17 343:9 346:11 professing 310:15 professional 1:16 102:3 profile 35:14,17 program 250:14 255:20,21,24 289:19 programmatic 29:23 133:4,16,18 144:25 326:9 336:11 programmatically 72:3 149:15 221:8 227:18 305:25 342:14 programmed 170:23 programming 133:20 326:14,22 327:5 342:3 programs 244:21 250:10 251:22	projecting 127:5 projection 127:2 projections 126:23 promise 247:24 promptly 182:12 pronouncing 85:2 proof 65:12 209:17 proper 65:11 97:9 136:20,21,22 260:21,25 261:4 270:6,9,23 323:23 324:5 properly 76:23,24 83:10 125:13,13 property 179:15 proposal 220:13 254:16,18 propose 189:16 191:6 320:6 proposed 53:6 57:22 63:6 90:8 90:10 115:17 128:6 164:22 177:23 214:17 233:24 239:16 251:17 254:23 319:2 329:2 337:18 347:5 proposing 168:10 216:19 240:3 251:16 255:4 proposition 317:7 proprietary 142:22 143:2 326:20 327:5,19 328:3 protective 13:14 13:17,20 87:6 259:11 279:6 319:16	protocols 11:12 proven 324:9 provide 78:23 83:3 99:10 200:19 214:6 220:14 222:19 223:4 238:18,25 239:13 250:10 308:13 316:17 provided 27:13 32:4 39:20 45:24 196:20 205:4 214:16 227:4,5 240:14 provider 83:4 235:10,12 307:23 providers 79:11 provides 89:11 120:6 235:20 243:16 providing 89:15 178:19 235:15 provisions 184:15 proviso 75:17 220:19 proxy 164:21 165:3 216:17 345:17,19 public 1:17 165:4 248:3 329:17 355:19 publically 159:14 published 160:6,9 pull 13:23 21:18 32:9 36:23 38:8 45:13 47:7 109:15 183:7 201:19 232:24 243:13 247:6 295:25 329:14
--	--	--	--

[pulled - ran]

Page 48

<p>pulled 100:7 272:25 pulling 107:14 purchase 122:5 125:4 156:13 158:17 189:11 195:10,15 226:18 231:18 332:3 338:25 345:16,19 347:18 purchased 109:22 174:7 189:18 203:16 204:4,4 216:4 225:20 240:19 306:24 333:11 339:4 purchaser 222:8 purchasers 225:9 purchases 25:2 115:7 126:2 141:17 156:21 158:5,7,12 166:12 176:5 188:23 218:22,25 219:20 221:11 227:4 231:13,16 239:9 336:9 338:14 347:17 purchasing 158:22 purity 44:2 purports 32:20 purpose 28:13 34:4 59:21 79:10 105:22 124:14 135:23 136:4,18 172:18 174:14 175:24 179:20 209:7 229:12 233:14 252:7 253:5 259:7,16 283:10</p>	<p>purposes 10:5,6 20:15 24:5 33:8 34:3 44:7 78:25 107:23 109:19 120:8 124:19 128:2 135:16 137:23 181:3 210:25 236:11 272:10 276:16 283:5 285:17 297:25 307:24,24 328:21 pursued 323:18 push 83:17 put 15:16 20:13 36:21 44:23 45:14 51:21 76:16 129:2 157:2 160:5 163:7 228:14 254:14 264:18 292:14 331:18 335:12 341:5</p>	<p>217:10 334:8 question 11:25 12:9,23 15:10,17 18:4 25:20 27:10 38:21 43:3 44:5 53:11 55:2 59:5 60:25 65:22 66:5 66:13,17 71:25 73:21 75:12 76:10 79:2 80:9 81:18 85:18 90:6 95:10 97:11,16,21 99:6 99:13 105:21 108:6 113:22 115:9 121:24 125:12 130:20 135:18 147:16 149:21 155:13 157:11 158:4 164:4 165:23 168:7,20,24 173:14 174:11 175:19 183:21 184:21 191:13 192:25 193:8 194:21 195:12 198:20 199:10,17 199:20 200:8,17 201:16 207:19 210:25 211:10,15 211:17 212:9 214:4 217:18 219:18 222:16,17 222:22 228:12,14 228:15,22 229:19 239:12 240:21 242:15 243:19 258:7,24 266:21 280:25 281:18 296:14 307:19 309:23 315:11,12</p>	<p>316:12 320:2 321:8 324:16 332:6 337:24 343:24 344:12 questioning 154:12 349:24 questions 13:4 18:2 52:9 58:17 61:3 66:3 92:13 101:15 109:18 119:4 129:2 203:11 260:11 272:11 278:13 305:2 317:25 321:18,24 322:21 328:22 350:2,7 351:6 quick 26:14 108:22 151:7 154:15 278:13 321:23 322:6 quickly 155:12 quite 25:25 31:12 70:14 75:13 89:18 92:17 155:12 158:6,18 165:8 166:6 218:24 270:14 296:19 297:15 298:6 318:4 quote 93:24</p>
	<p>q</p>		
	<p>qualification 338:22 qualified 44:2 201:5 qualify 200:20 332:5 337:6 qualifying 87:25 88:12 319:3 quality 43:25 45:11 quantify 301:12 301:23 quantities 330:15 330:24 331:17 332:4,21 349:16 quantity 189:8 206:2 207:9,11,13 207:15,16 208:23</p>		
			<p>r</p>
			<p>r 1:8 2:2 3:2 4:2 5:2 6:2 7:2 8:11 8:15 9:17,17 10:14,15,15,15 117:21 354:3,3 raise 92:23 raises 25:16 ran 46:11</p>

[range - record]

Page 49

range 309:20	189:23 266:25	reasons 303:18	350:23
ranges 210:23	284:8	313:21 317:3	recognize 64:18
rapid 245:16	reads 296:8	rebecca 3:14	276:9
rapidly 304:24	ready 151:24	recalculation 42:8	recognized 241:16
rare 130:24	152:4 153:10,21	recall 30:12 110:5	recognizing 303:8
131:10 150:24	193:21 232:5	110:20 119:19,21	recollection 28:10
293:11	real 11:23 26:14	119:25 120:17	103:3
rarely 301:8,9	310:13 313:8	121:4,6 148:8	recommend
raspanti 5:12	reality 83:14	190:13 193:3,6,10	180:13
rate 158:13 330:25	194:17 303:5	193:21 194:3,4,15	recommendation
raton 3:10	realize 52:23	225:22 252:25	346:2
raw 19:14,20,20	350:3	326:18 344:10,19	reconcile 170:14
28:5 29:24 30:8	really 25:18 86:12	344:21 347:11,19	279:17
30:11,17 32:3	94:18 109:17	347:23 348:9	reconciliation
33:10	131:19 132:14	349:10	256:2
raymond 4:6	173:11 184:18	recalled 109:23	reconvene 61:24
reach 179:22	214:11 217:15	112:3 119:15	record 9:3,13 10:4
reached 77:13	247:22 257:9	122:19 193:14,19	10:13 13:10 17:18
141:20 320:17	264:3 268:14	193:25 194:8,12	18:8 19:17 34:10
reaches 272:6	287:19 290:13	345:25 347:18	34:11 37:20 62:7
read 17:18 21:8	291:10 306:21,25	348:13	62:12 109:7,12
37:22 39:25 44:20	312:6 339:24	recalls 110:12,17	114:13 116:6
45:5 53:20 55:2	341:4 346:13	112:3 119:5	117:16 120:2,3,25
85:16,22 99:11	realtime 116:15	160:10 193:20	121:2 132:2 151:2
105:4 110:20	reason 24:9 38:2	194:18	151:10,12,17
116:18 117:11,16	58:16 67:19 75:17	receipt 353:18	152:7,18,20,22,25
171:22 202:11	88:8 125:12	receive 122:10	153:3,5,15,18,23
203:10 231:10	160:24 167:21	received 23:21	154:8,17,22 182:3
234:14 243:21	201:15 205:25	104:3 122:18	182:25 183:6
263:12 267:18	224:20 226:21	167:10 168:19,20	200:14 205:24
284:17 305:11	227:9 229:25	169:14 171:10	215:14,16,22,23
341:5 351:7 353:9	241:3 244:3	172:2 193:14,19	232:15,20 295:15
355:5	257:16 263:19	233:3 239:20	295:20 318:23
readily 93:5,23	314:12 345:21	receives 83:15	322:11,15 328:9
94:15 95:8 97:21	347:9 353:11	97:9 234:25	332:19 334:14
111:18 144:25	354:6,9,12,15,18	305:24	335:24 340:5
160:12 165:3	354:21	receiving 83:24	342:12 343:16
238:2 250:18	reasonable 214:13	235:6	344:2,22 347:6
290:9	reasonableness	recess 62:8 109:8	348:10,13,22
reading 44:18	214:6	183:2 232:16	350:17,22 351:2
53:10 134:6 155:9		295:16 322:12	352:7

[recorded - removed]

Page 50

recorded 9:5 75:3 141:17 293:20 325:2 recording 67:23 80:19 recordkeeping 55:16 records 25:23 34:14 35:18 70:6 80:7 119:17 123:5 139:25 174:15 175:8 192:11 219:10 230:11 254:9,11 259:21 263:23 303:16,16 305:9 336:12,19 341:5 343:2 recounting 341:7 recovery 7:5 19:21 red 133:14 redundant 72:25 reefer 5:17 refer 53:24 112:24 113:10 135:22 136:6,17 151:22 162:7 219:18 271:5,13,14 272:12 273:24 281:20 296:7 328:20 330:13,14 reference 57:18 133:24 282:11 referenced 40:5 108:11 131:12 135:21 353:6 references 301:18 referred 37:22 91:23 179:3 278:12,16 322:24 referring 18:22 30:14 48:14,17	63:3 65:3 86:17 96:4 106:10 112:18 117:24 118:12 124:4 128:5 134:13,14 179:7,10 184:23 206:5 270:4 273:23 281:3,17 329:21 refers 57:16 105:25 106:3,5 190:6 245:23 248:2 refill 153:17,24 344:18 reflect 26:24 51:5 115:18 239:18 266:11 268:24 reflected 30:24 32:3 118:18 147:21 202:7 reformatting 30:2 refreshed 18:18 refund 118:13,16 119:12,16,20 120:18,25 121:16 122:11,18 123:20 refunded 122:3,4 refunds 115:19 116:3 120:2,7,19 121:2 123:4,10,15 refuse 306:19 regard 69:18 74:5 131:24 257:14 287:14 288:6 regarding 9:6 58:9 192:16 197:25 regardless 76:7 143:20 144:21 249:13 262:25	regards 28:3 registered 1:15 238:25 regularly 78:6 regulated 135:9 regulations 62:24 63:13,21 184:14 256:22 257:3 regulatory 72:5 reimbursed 303:2 305:20 307:25 reimbursement 310:24 reimbursements 239:3,10 relabeler 50:10,13 50:20 51:9,19 relabeling 52:4 relate 56:11,20,20 58:18 204:23 related 83:16 84:15 119:5 288:17 323:12 352:10 relates 55:14,16 56:12,24 205:19 relating 55:12 81:23 relational 138:15 relations 312:22 relationship 82:18 132:17 134:16 150:17 155:25 156:3,8 187:9 266:24 285:9 289:10 306:5,9,18 307:5 310:10 312:5 relationships 133:3 146:25 147:23 150:3	156:12 163:3,4 245:3 288:15 298:18 304:6,15 310:16 relative 335:11 relatively 196:11 196:11 relevant 70:18 76:22 78:16 85:18 89:25 91:16 94:4 147:6 160:25 173:17 reliable 180:9 reliably 304:24 reliance 131:16 relied 8:12 22:15 22:20 26:23 31:10 31:13,16,22 32:2 43:2 64:11 108:9 127:10 215:5 rely 33:10 43:5 230:15 251:17 255:2 remained 258:20 remaining 347:23 remains 296:11 remember 16:13 172:4 291:8 remembering 192:8 234:13 remind 13:9 19:15 99:15 250:4 294:18 reminder 259:14 remotely 1:17 remove 229:11 236:6 removed 111:17 111:22 230:5 234:4,6 236:13
--	---	--	--

[removing - retailer]

Page 51

removing 229:12	123:25 126:19	303:8 322:19	308:24
rena 23:20	127:17,24 147:22	representations	resolved 171:2
rename 170:9	157:2 159:15,21	102:19	304:5
rendering 98:11	163:19 168:5	representative	resolving 75:11
reorder 190:16,17	177:4 179:13	76:13 128:22	respect 53:15
reordering 190:5	180:7 183:8,11	130:6 145:22	85:12 86:20 90:12
repackager 50:20	190:6 195:2	313:23	123:20 157:16
51:9	205:15,19 210:15	represented 44:2	189:17 227:15
repackaging 52:3	214:10 215:20	253:14 264:7	292:19 296:14
repeat 269:4	220:3 222:18	269:20	311:5
repeated 46:23	223:2 236:25	representing 76:5	responding 313:7
repeatedly 305:23	240:15 249:22	represents 59:23	response 133:16
346:3	250:17 256:10,17	71:8 255:3	272:3
rephrase 73:22	257:20 260:6,17	request 53:14 70:2	responsibilities
85:10 113:22	261:7 270:6,25	71:3 78:11 154:19	270:19 309:20,22
replacement	280:14,20 284:11	256:10	responsibility
344:20 346:4,16	285:4 311:24	requested 197:24	286:9
347:4 348:15,22	313:4 320:7	requests 15:7,14	responsible 72:8
349:20	324:13 328:8	77:22,25	83:7 128:7 269:16
replicate 31:18	329:9	require 178:17	314:16
103:15	reported 103:12	183:15 226:19	responsive 15:12
replicating 159:13	116:4 126:13	274:25 275:6	15:23
report 16:4,6	150:15 158:3	332:20	rest 126:23
18:14,15,17 21:9	163:15 165:16	required 134:17	restart 147:14
22:21 23:4,9,12,20	206:3 272:22	177:17 184:24	restate 11:23
23:22 24:15,23	274:17 281:6	185:18,22,25	202:21
29:11 32:19 33:5	reporter 1:16,17	186:4,19 268:10	restricted 40:17
37:5 38:23,25	9:10,14 38:6	321:12 355:13	restroom 108:21
39:4,8,19,23 40:6	116:18 117:10,11	requirements	result 27:24 161:5
40:12 41:3,6 42:6	117:17 124:7	55:17 143:7	166:18,19 194:5
42:12 43:18 44:18	147:2	144:19 177:20	238:19 290:16
45:14 47:4,18	reporting 72:5	requires 54:23	resulted 178:16
52:24 54:2,12	127:9 160:15	83:20 307:3	results 29:21
55:7 63:17,23	reports 71:12	requiring 200:9	46:24 216:9
64:6,12 67:14	87:14 99:19 108:9	requisite 333:14	retail 8:13 32:21
68:25 69:9 71:21	135:11 279:25	researched 105:16	33:6,19 34:7
81:9 84:13,15,16	282:4 327:16	reservoir 72:25	36:13 100:9
85:16,18,23 87:16	represent 26:23	residual 224:9	127:14,15 163:23
96:4 100:20	76:24 170:10	resolution 76:7	204:17 317:22,23
111:21 112:4	187:15 225:23	resolve 70:24	retailer 34:5,18,20
120:6,18 123:18	276:9,10 301:19	74:10 277:18,25	34:23 55:23 70:4

[retailer - rows]

Page 52

70:13 78:17 165:7 165:17 186:18 198:4,23 255:6 334:22 342:23 retailers 18:19,21 69:19 70:19,20 74:6 100:7 198:16 retain 34:14 195:5 196:18 retained 15:24 25:6 307:22 retains 308:14 retention 55:25 retirement 248:4 retrod 260:10 return 119:14 142:2 264:23 272:3 283:7,18 353:13,17 returns 116:10 117:21,23 119:4 119:17 121:6 reveal 279:5,8 revenue 71:24 164:2,8,11,21 revenues 164:18 reversed 116:10 revert 143:10 review 20:22,22 20:24 23:25 81:11 81:22 104:8 105:20,22 107:2 107:13 177:12 197:15 210:18 353:7 reviewed 18:14,15 19:11,24 20:5 23:3,19,22 43:4,15 105:16 170:19 236:24 334:17 345:18	reviewing 23:8 24:14 34:5 77:23 revision 42:6 revolving 91:3 reword 108:5 rich 138:5 richards 10:15,19 right 10:23 11:16 16:10 19:6 20:11 21:15,17 22:13,16 30:22 31:3,8 32:23,24 35:2,3 36:17,18,21 37:4,7 39:16 42:23 43:17 45:6,20 46:16 47:13,19,20 48:5,8 48:13 49:20 50:5 54:8 56:6 57:13 59:15 60:12,16 61:7 62:13,18 77:6,9 81:19 82:16,20,24 87:19 88:18 95:16,25 96:8 102:16 108:18 112:19 115:21 116:2 120:10 124:9,13 125:18 126:8,25 129:6,24 130:14 132:19 134:11 135:2,25 146:25 147:24 154:20,24 155:6 156:3 157:4 158:12 166:4,16 173:21 174:19 177:7,14,24 179:13 183:17 186:14 187:12 191:9 192:9 193:6 194:9,19 195:18 197:3 198:24	201:24 202:8 203:10 204:9 205:7 206:22 209:4 210:4,19 215:16 219:16 232:23 233:11 234:18 235:4,14 236:3 240:13,15 240:24 241:12,19 244:12 246:2,3,11 246:18,19 247:3 248:4,22 249:12 255:9 256:9 260:5 261:12,19,24,25 262:16,17 263:10 264:4,10 265:12 266:9,15 267:17 267:25 268:11,12 268:22,23 272:7 272:21 274:5 278:21 280:13 285:23 287:13 290:25 292:6,21 294:19 296:6,20 297:10 298:2 299:17 300:22 302:11 303:9 305:21 307:16 309:5 315:9 316:21 317:10 318:2,9 319:6 321:22 322:3 323:19 324:22 325:2 328:12 330:7,21 331:9 334:9,10,14 335:4 338:5 339:13,21 341:13 342:17 346:18 348:3 rise 167:14 287:12	risk 66:22 71:19 209:18 235:18 244:23 288:2 314:16 rite 5:21 rivero 7:4 road 7:13 robustness 26:3 rockett 6:16 rodeo 178:14 rogue 224:23 role 81:24 317:16 rolling 169:5 rolls 173:10 room 16:16 17:15 139:24 154:4 rooney 5:4 rose 4:19 ross 4:21 roszel 7:13 rough 229:20 roughly 11:7 41:3 41:6 42:17 57:9 89:21 103:2 round 307:6 route 260:18 routed 136:20 265:25 routes 306:15 routine 279:10,23 279:23 routinely 34:14 69:15 94:11 125:7 194:18 216:7 230:14,18 268:2 274:14 row 47:25 49:13 49:18 158:11 247:11,13,15,17 rows 48:21
--	--	--	---

[rpr - see]

Page 53

rpr 352:3,19 ruben 117:2 rule 231:20 286:5 286:16,18 308:25 338:12 rules 10:7,8 135:12 176:13 256:23 338:5 ruling 99:11 200:3 200:15,16 rulings 200:10 run 30:5 40:3 283:4 327:13 rundown 26:11 73:3 running 40:6 rx 95:14 163:11	76:19 77:2 88:17 103:16 118:17 131:3,5 132:14 139:19 140:11 149:25 150:8 152:12 154:10 163:22 164:20 166:19 167:16 172:23 176:4 179:25 180:11 185:6,7 189:4 207:19 209:15 219:8 228:16 231:11 241:22 252:10,20 254:2 292:4 294:7 297:9 297:11 300:5 304:8 305:5 306:4 306:6,7 308:22 314:8 says 32:22 47:25 48:2 49:4 53:2 62:22 76:17 81:8 106:25 125:8 133:8 138:9 146:11 148:16 171:23,24 191:20 197:6 205:22 222:18 226:23 230:15 241:12,14 263:17 277:11 283:18 292:25 309:2 311:25 312:6 341:15 348:6 349:8 scale 340:2,4 scenario 129:3 309:6 311:16 313:2 349:17 schaffer 2:18	schedule 12:13 52:2 107:18 182:19 336:9,10 336:24 347:15 science 216:5 scientific 214:23 345:18 scigen 6:21 scope 40:17,23 53:22 57:20 193:23 210:9,15 212:7 214:10 237:21,24,25 241:6 284:15 324:3 325:13 scratch 295:8 screen 14:8 31:7 40:13 45:6 47:16 101:19,25 146:20 202:19 247:23 scripts 27:2 223:22 312:19 scroll 37:8 48:20 247:8,11 330:4 se 3:22 search 230:11 second 78:8 83:9 89:8 106:2 130:13 130:19 136:12 147:12 149:25 152:11 202:18 229:24 247:10,14 247:15,21 272:5 305:13 secondarily 25:22 secondary 52:16 179:25 258:3 307:6 seconds 26:20 141:22 150:20 151:5	section 55:4 183:10 sector 245:14 secure 17:13 securing 130:5 security 55:19 183:13 sedran 2:14 see 15:6 16:20 31:22 34:19 40:15 44:14 46:24 47:23 48:21,24 55:14 56:7 77:24 80:21 80:21 86:16 96:15 96:16 103:15 105:24 107:16 109:2 116:8 122:7 122:10 127:22 132:5,13 137:14 139:12,13,14,14 139:17 142:12 146:9,19 158:10 158:13 159:7 160:4,13 165:25 175:21 176:14,18 178:5 179:7 192:7 201:9,16 206:5,11 222:20 230:11 242:6 243:15 245:19 249:11 251:21 253:16 257:10,11 262:18 263:15 273:19 279:20 280:3,3,4,5 282:16 284:10 287:21 291:13 294:9,15 295:7 297:15,16,18 298:19,22 299:3 305:3 306:18 321:17 330:8
s			
s 2:2 3:2 4:2 5:2 6:2 7:2 8:8 10:15 354:3 safety 46:7 sake 26:18 38:5 sale 46:7 112:14 114:21 115:5,10 115:19,21 sales 164:19 188:23 sample 77:24 94:2 94:3 99:24 samples 169:6 171:9 sara 1:15 9:10 352:3,19 sass 327:13 sat 145:22,25 saw 11:3 186:16 250:15 255:17 313:2 316:24 saying 30:20 43:21 59:10 68:6 72:21			

[see - show]

Page 54

337:18 338:15 346:6 347:3 349:17 seeing 289:21 311:20 seek 68:10,11 349:3 seeking 320:3 seen 14:23 15:9 84:6 140:20,22,24 141:6 142:7,8,10 198:22 199:7 274:16 275:5 277:20 301:6 316:25 317:8 344:7 segment 50:17,18 51:15 segmented 105:16 segregable 83:21 segregate 71:23 80:25 269:6 290:8 294:5 segregated 83:5 segregates 306:14 segregation 84:5 304:22 self 72:7,17 75:5,6 76:18 80:11 99:4 99:7 134:19 221:2 221:3,7,16,25 222:13 223:14 242:16,21 243:6 243:18 248:12,20 267:16 280:23 285:21 287:6 289:13,15 290:15 291:9,17 293:4,19 293:19 294:25 296:10,25 297:3 297:16,23 300:12	300:19 301:17 302:6 303:22,23 304:10,12 305:4 307:21 308:19,24 312:7 316:10 sell 34:7 156:14,16 190:23 selling 50:11 sells 185:2,15 290:3,4 send 17:18 74:25 120:3 265:22,23 308:10 sends 137:18 148:10 sense 11:4 19:10 102:21 111:11,15 132:6 237:18 264:24 265:2 337:5 sensitive 190:22 sent 27:11,16 29:16,19 102:5,15 120:4 138:14 152:3 265:17 353:14 sentence 53:24 57:15,16 62:22 63:4 94:14 133:24 134:7 205:22,22 206:5 258:19 271:6 284:15 286:6 292:25 296:7,15,18 316:4 sentences 284:17 separate 55:12 72:16 81:3 155:24 156:12 187:11 256:22,23 273:18 274:19	separated 125:21 separately 41:4 97:8 163:17 220:22 229:8 249:16 separating 86:22 september 105:19 105:25 106:3,18 106:23,25 series 15:6 serious 25:16 seriously 94:5 service 83:4 130:5 131:21 234:17 235:24 236:19 237:6 249:7 250:2 250:23 services 100:25 101:6 102:3 129:18,24 131:11 131:25 132:7 133:13 137:10 235:18 250:9 285:14 287:18 290:4 291:11,15 316:20 326:21 327:22 session 297:21 set 33:25 52:9 71:4 74:13 78:23 79:7 79:9,22 80:3,13 81:6,22 91:20 96:5,6,22 97:6,11 100:12 134:22 139:9 169:15 172:4,7 173:10 174:19 175:8 192:18 197:9,11 269:17 272:14,24 273:12,24 283:3 294:13 314:9,12	314:21 315:5,15 349:12 352:6,15 seth 3:12 200:14 sets 27:18 170:20 173:15 202:24 231:20 337:3 setting 144:11 287:13 315:2 settlement 230:18 settlements 178:17 seven 42:21 114:9 172:13 229:21 247:11,12 335:14 335:15 349:23 shaking 272:16 shape 69:17 share 157:7 161:2 161:4 164:6,22 198:12 251:23 280:3,4 329:17 shares 167:19 sharing 260:23 sheet 79:24 353:11 sheets 97:12 273:12 shevron 6:16 shield 81:3 263:15 263:19 312:8,10 312:11,16,18 shift 177:2 245:15 shifted 235:19 ship 36:12 shipped 192:12 short 20:3 29:16 39:13 226:14 shorter 161:8 show 29:20 32:20 35:21 190:2 195:22 214:17 247:22 251:20 285:24 288:24
--	--	--	--

[show - sources]

Page 55

291:11 292:20 312:2 327:15 showed 34:24 197:17 showing 26:21 33:2 104:9 198:23 253:5 324:16 shown 14:7 18:5 33:9 101:25 146:20 149:23,25 168:11 171:12,14 235:25 shows 157:6 196:24 346:16 side 44:23,23 45:15,15 157:2,3 280:16 sign 21:24 149:15 351:8 353:12 signature 39:3 352:18 signed 353:20 significant 131:6,8 silos 63:25 similar 67:23 145:11,13 168:7 318:21 346:12 simple 201:8 203:12 336:11 simplifying 224:2 simply 10:19 19:14 33:16 40:22 72:12 89:20 191:20 221:8 235:5 251:13 269:3 279:9 304:7 339:16 simultaneous 24:24 simultaneously 204:15	single 27:20 28:15 66:4 67:5,12,24 69:2 81:2 126:3,3 126:4 160:20 168:21 171:15 175:23 213:16 229:6 275:6,8 304:14,19 306:23 321:2 344:5 sit 51:25 52:6 78:4 296:20 325:20 341:4 sites 259:6 sitting 139:24 142:13 situation 204:25 286:11 288:9 291:25 301:24 312:17 328:5 situations 287:5 297:23 348:12 six 55:7 56:3,12,22 100:19 105:16 109:16 157:8,17 157:19 161:21 166:10,13,24 168:11,21 170:11 170:19 172:11 174:12 176:8 295:19 302:23 320:25 331:4,5,6 335:18 size 255:12 skeptical 37:9 skimmed 19:14 skin 67:2 skip 11:22 skipped 74:24 147:3 317:22 slightly 27:21 207:20	slow 244:21 slowly 21:9 small 69:11 99:24 105:4 158:6,18 177:19,19 220:23 227:7 251:23 252:22 303:15,24 305:7 smaller 41:23 161:9,11 174:19 smirk 152:11 smolij 3:15 softer 170:15 software 133:20 141:7 142:18,19 142:23 146:12 326:14,21 327:5 327:11,14,14,20 328:3 342:4 solco 3:7 9:25 sold 34:11 43:23 46:3 50:10 110:14 165:17 194:4 343:9 solely 115:20 251:17 solutions 353:23 somebody 80:15 214:11 285:14 289:3 333:13 somebody's 285:12 somewhat 12:20 sophisticated 127:5 sorry 24:22 54:24 68:14 84:18 95:19 104:13 126:16 127:15 136:7 137:6 138:20 147:12 149:5	150:10 187:19 199:17 202:17 219:17 225:11 228:11 234:7 262:8 264:12,12 267:9 274:15 278:9 293:24 306:12 331:9 344:24 sort 14:11 30:16 52:8 53:2 61:4 64:15 67:21 72:15 77:14 81:11 84:14 108:19 116:15 118:13 246:14,16 297:22 337:9 sorts 310:16 sought 77:23 sounded 228:18 sounding 66:23 sounds 62:2 155:10 source 25:11,16 51:7,13 67:5,12 69:3 77:12 78:8 78:22 79:7 84:2 159:12 160:13,20 178:4 189:6 191:12 252:2 256:3 278:5 314:5 343:12 sourced 159:8 sources 18:16 19:23 25:18 31:13 51:12 64:13 67:2 67:15,17,20 72:11 73:18 74:15 111:20 161:20 165:5 180:2 189:13 191:15 192:5 238:16
---	--	--	---

[sources - stanoch]

Page 56

240:3 253:2,10 257:19 258:3 277:10 318:5 south 5:22 speak 103:7 144:15 speaking 52:3 96:20 116:25 171:8 190:24 special 199:23 200:10 specialty 164:18 specific 53:22 57:18 65:15 66:5 69:19 91:20 93:2 111:21 112:18 113:21 114:14 115:6,17 118:9,18 129:3 136:5 142:3 146:12 157:12 160:3 170:5 173:18 185:8 189:4 191:8 193:10,24 198:8 201:10 208:8,25 212:11 256:19 267:6 279:8 285:16,16 298:21 323:12 332:7 334:2 337:19,21 specifically 19:8 40:8 97:7 106:10 106:19 119:4,24 133:24 134:13 136:6 146:23 149:23 165:9 186:5 194:8 198:4 202:3 242:24 243:24 256:21 259:16 263:21 292:5 293:3	306:13 339:25 specifics 140:4 169:11 171:5 specified 170:18 specifies 125:5 207:15 speculation 208:24 300:25 313:5 speculative 302:15 309:12 311:11 spell 10:13 spells 170:14 spend 20:17 21:5 26:19 86:9 101:14 spent 23:8 102:24 103:4,18 split 272:5 spoke 155:11 sponsor 72:17 75:5 99:7 286:13 287:6,25 296:20 296:25 297:4,17 300:12 304:12 305:4 308:19,25 sponsored 227:24 238:24 287:21 sponsors 89:23,24 177:16 301:17 304:11 spot 224:23 spouse's 226:5 spouses 226:4 spreadsheet 8:22 233:3 247:10 spreadsheets 27:9 sprung 5:25 spun 304:18 stable 245:2 staff 24:11 103:18	stage 193:20,21 stand 290:16 standalone 266:13 standard 59:7 65:11,25 94:14 100:12 121:25 127:9 143:21 144:2,7,10,10 159:8 220:6,8 271:18 274:20 278:3,7 306:22 327:11,13 standardization 279:22 standardized 159:21 standardizing 28:14 standards 58:22 72:5 144:16 standing 269:2 stands 105:11 stanoch 2:8 15:16 17:20 19:12 24:7 32:6 33:13 36:8 37:12 38:18 41:17 43:7 44:12 45:7 46:17 49:8 50:6 51:10,24 53:17 54:9,17 56:14 58:12 59:16 60:17 62:3,16,20 64:2 65:18 68:12,17 73:14 74:17 77:17 79:5,13 82:4,21 85:8 87:3 88:19 90:13 91:11 92:6 92:20 93:11 95:17 96:9 98:3 100:5 101:2 103:5 104:5 106:13 108:13	109:25 111:7 112:20 114:3,24 115:22 117:2 118:20 119:9 120:11 121:17 122:20 123:21 124:20,24 129:7 130:15 132:20 134:12 135:3 136:2,25 140:12 140:23 143:3 144:3 145:17 147:7 150:4 151:8 151:16 152:8,19 152:23 153:4,8,14 153:19,20,23 154:2,10,16 155:7 155:20 156:4 157:21 162:13,16 164:14,23 167:4 168:12 169:16 171:17 172:14 175:11 177:25 180:18 181:8,21 181:25 182:4 183:18 186:24 187:25 188:16,25 192:21 193:15 194:13 195:24 196:6,10 197:19 198:25 199:11,20 199:22 200:7,22 202:9,13 203:19 204:10 205:8 206:25 208:4,13 209:11 210:5 211:5,24 213:20 214:19 215:17 216:22 217:13 218:6 222:5,24 226:7 228:11,20
--	--	--	--

[stanoch - subject]

Page 57

230:7 231:4 232:2 232:9 237:11 239:21,24 240:16 241:4,20 242:12 243:22 248:13,23 250:6 251:3,10 252:17 254:20 255:15 256:6 259:9 266:17 269:11 270:12 275:2,20 276:21 279:4 280:15 281:25 282:22 284:13,24 286:22 291:2 292:7,22 295:9,12 296:4 298:11 299:5,18 300:23 302:12 308:4 309:10 310:2 311:7 313:18 315:10,20 316:22 318:15 319:12 320:12 323:3,25 324:11 325:11 326:3,17 326:23 327:7,23 328:13 329:7 331:20 332:25 336:3 337:22 340:18 342:18 343:19 344:23 346:19 348:18 349:21 350:5,15 351:3,4 353:1 stanoch's 202:22 start 26:16 65:20 68:9 69:6,14 73:25 176:12 252:10 288:9 289:7	started 335:13,14 starting 53:2 160:11 260:16 state 6:22 10:12 11:15 25:21 35:22 36:12,12,15,15 58:18 125:22 126:3 234:8,9,16 235:10,11,13 240:11 242:17,23 243:6,7 244:2,7 245:8,18 246:21 247:3 249:9,21 250:13,25 251:7 251:22 255:19,20 255:21,24 256:4 256:12,14 257:7 257:14,22,24 259:20 state's 258:21,25 stated 146:5 296:17 statement 45:10 75:14 112:9 123:7 159:5 195:13 220:20 226:22 290:17 313:17 states 1:2 36:6,10 55:18 127:12 256:24 257:25 260:3 stating 37:14 200:7 statistical 27:22 213:5,10 327:14 342:3 statistics 69:8 status 92:13 94:17 110:5 244:5,11 245:8,12,20 248:17 253:24	259:19 266:12 268:25 273:16 293:4 327:12 stay 107:7 154:9 160:20 215:12 stays 260:17 stellar 253:7 stenographic 1:13 9:13 step 12:21 31:18 50:21 57:11 66:7 76:20 112:12 113:16 123:6 223:9,9 255:11 257:5 277:8 305:13 339:23 340:16 349:6 steps 73:10 steven 4:16 stick 350:13 stock 116:11 stop 53:10 105:8 134:6 152:9 256:10 284:8 345:24 stopping 154:23 storage 163:7 store 36:14 store's 35:13 storefront 164:19 stores 3:8 straight 321:19 straightforward 169:25 straightforwardly 166:6 strategy 107:7 street 2:6,16 5:6 5:14,22 6:6,14,22 strength 113:13 206:2 207:12	333:10 338:25 339:14 strengthens 24:19 strengths 174:9,23 stress 75:16 strike 90:6 103:10 103:14 108:5 147:16,17 193:2 197:13 224:25 230:20 307:18 342:9 344:13 strong 288:20 strongly 65:21 structure 80:5 137:18 141:15 148:2,4 180:2,4 248:16 268:19 274:13,20 275:10 298:4 310:9,10 311:19 structured 84:4 97:13 148:11,18 314:21 structures 277:14 struggle 180:23 studied 28:15 studies 215:3,3 study 52:2 157:16 215:4 stuff 304:18 stumbling 58:16 sub 236:8 274:10 subclass 203:24 204:9 205:7 subclasses 189:18 191:8 202:6 203:3 204:16,20,23 subdivision 114:7 subgroups 321:6 subject 13:14,19 15:14 87:6 90:17
--	---	--	---

[subject - systems]

Page 58

98:9 167:6 168:15 207:6 214:9 218:8 223:6 256:22 279:6 303:17 subjectively 305:11 submit 217:5 submitted 16:7 38:23,25 264:18 suboxone 84:25 subpart 187:14 338:22 subpoenaed 100:15 subscribed 355:14 subsequent 239:10 subsequently 157:10 subsets 169:6 253:17,22 subsidies 239:3,11 239:18 substance 39:22 76:10 212:11 substantive 25:20 27:25 108:3 subsumed 187:13 successors 220:11 221:20 222:3 223:9,11 suffered 59:14 sufficient 139:4 148:11,13,18,23 149:6,14 177:22 191:21 195:6 196:20 260:20 305:25 308:23 332:3 suggest 57:6 61:21 72:24 94:7,10 158:24 231:25	suggested 98:20 98:24 123:8 suggesting 133:11 194:23 216:24 345:10 348:21 suggestion 69:6 suggestions 25:9 suggests 57:3 99:5 137:8 sui 143:21 suit 319:6 suite 3:9,22 4:21 5:6 6:6 suited 283:4 sum 235:13 summarize 33:5 summarized 103:9 summarizing 43:20 summary 8:13 32:17,20 53:21 56:7 159:9 summed 66:18 summing 339:16 super 12:6 39:11 44:22 supplement 78:9 supplementation 74:7 supplemented 70:5 178:9 supplementing 42:16 supplied 24:5,10 28:4 30:7,9 40:10 88:6 93:24 94:3 98:20 100:4 140:5 176:7 185:7 191:11 205:13 239:5 257:17,18 258:15 346:9	supplier 113:17 191:17,19 192:17 204:17 suppliers 291:9 supply 15:23 41:24 55:19,21 71:14 183:12,23 189:7,12,13,23 190:18 191:15,20 213:8 330:24 333:11,14,20 338:24 341:22,22 341:22 supplying 192:18 support 148:14 196:22 252:24 284:10 313:17 supported 25:9 135:16 304:21 suppose 76:4 212:8 346:7 supposed 117:7 supposing 17:8 sure 10:14 12:17 17:24 26:9 28:17 29:8 37:10 39:10 57:20 60:11 73:8 73:19 82:16 85:22 90:20 107:17 119:7 127:23 128:3 138:25 141:5 142:12 155:12,14 169:2 174:13 181:12 187:21 188:11 198:20 206:21 211:17 212:4 217:20 229:23 241:12 252:19 254:25 255:22 256:25 260:14	262:20 269:23 275:14,15 278:24 292:19 297:20 309:24 315:24 319:25 328:24 339:9 350:10,19 surprises 107:18 surrogate 117:25 surveys 64:15 131:17 sustain 307:3 swath 299:12,16 swear 9:15 swim 99:17 swing 251:24 switch 99:22 218:21 231:24 232:6 switched 218:15 333:16 switches 48:22 switching 144:12 219:4 sworn 9:18 352:6 355:14 symbols 117:21 synonym 67:7 synonymous 270:11 system 14:4 138:3 139:21 140:6,7,8 142:11 145:8 162:12 248:4 260:17 304:20,21 systematic 335:24 337:12 340:13 systems 143:12 144:12 186:9 189:24 190:2,9,14 254:15
---	--	--	---

[t - theoretically]

Page 59

t	332:15 333:13,17 338:8 350:23	109:14 138:23 163:13 175:22	territory 69:17
t 8:8 9:17 10:15	takes 28:8 130:2	182:17 189:6	testified 9:18
128:14 196:24	talk 14:9 131:14	207:21 249:8	46:10 318:3
197:2,4,6 354:3,3	177:8 187:8	253:24 255:9	320:16 322:23
tab 247:9,10	220:21 290:20	261:23 278:24	testify 16:13
table 33:9 157:6	291:20 328:6,8,17	282:15 290:9	testifying 10:21
157:12 159:8	330:22	296:4 308:18	testimony 1:8
160:5,7 168:5,11	talked 73:17 74:16	309:17	13:12 23:5,25
172:12	227:15 258:8	telling 38:6 42:17	29:9 70:13 74:19
tables 140:2	260:7 281:14	149:3 165:5 216:5	82:8,20 88:23
tablet 17:9	344:9	225:8 229:10	118:22 122:23
tackled 230:18	talking 14:12	307:6 324:24	144:4 148:9 150:6
tailored 349:12	19:19 26:10 45:19	tells 50:16 165:11	162:10,20 163:5
take 26:15 67:6	48:24 73:20 96:7	263:21 284:16	175:13 180:21
70:5 81:12,17	105:9 119:12	ten 11:7 21:10	199:16 201:3
87:24 97:20 98:13	133:4 134:21	61:15 99:20 114:8	216:23 236:23
101:20 114:20	143:20 144:8	146:4 245:10	248:25 260:8
122:17 139:7	163:22 172:5	tend 245:2	282:24 284:20
142:15 144:22	212:5 219:3 245:4	tendency 244:15	285:3 286:25
145:5 151:7 153:2	254:13 263:22	term 57:23 65:2	291:6 292:11
154:15 156:24	264:2 271:10	112:17 114:19	299:9 323:5
159:24 172:10	272:4 273:11,17	127:23 129:17	326:12,16 333:4
173:13 174:12	277:8 281:22	134:8 138:23	343:18,21 345:16
175:4,6,23 176:5	282:3,11,19	188:12 206:13,15	348:20 352:8
179:23 182:20	287:19 297:21	281:13,14	353:9,18 355:8
183:24 194:17	303:14 314:17	termed 172:3	teva 3:21 4:5
203:9 228:3	330:23 334:2	terminology 95:7	322:19
231:25 232:9	talks 45:16 162:4	118:14	texas 4:22
240:6 243:11	tallying 104:11	terms 17:7 20:5	text 44:19 243:21
244:23 280:7	tapped 72:24	33:21 53:9 63:6	thank 9:21 14:21
292:17 295:6	targeted 161:20	63:12,16 95:7	26:17 43:16 58:5
321:17,23 322:5	targets 162:9	143:8 145:4	68:3 77:9 85:4
331:3,4,5 340:11	task 260:4	182:17 184:12	104:17 117:15
346:3 347:21	tech 14:11 38:7	188:6 204:19	136:8 163:20
348:6 350:5,14	150:21	209:15 215:20	196:8 205:16
taken 1:14 10:5	technician 7:19	217:15 240:11	209:5 259:13
62:8 109:8 110:6	technologically	270:10 337:20	295:23
165:24 183:2	277:11	341:21	thanks 106:15
232:16 276:17	tell 28:25 52:2	terribly 125:25	theoretical 244:13
295:16 322:12	58:24 75:4,6		theoretically
331:8,15 332:10			131:4

[theories - time]

Page 60

theories 45:12	149:21 155:22	279:11 286:6,8	thrown 161:15
theory 224:22	156:10 168:2,6	291:21 296:7	tie 288:18
311:20 317:2	171:25 172:20	300:21 305:18,20	tied 263:2,5
therapy 339:4,17	176:12 180:9	307:16,22 310:22	tier 141:16
thing 21:23 39:24	188:5 190:8 200:2	310:24 317:20	tiffany 3:24
75:9 81:14 89:19	202:20 203:11	thornburg 5:20	322:19 329:22
95:5 103:17	211:9,14 227:17	thoroughly 21:9	350:16
106:23 122:6	228:23 235:2	thought 175:25	tight 12:20
170:10 202:12	240:6 241:22	183:21 343:13	tightly 107:7
216:2 225:2	244:23 247:9	thoughts 321:24	tim 236:25
276:10 279:14,17	254:24 263:17	thousand 255:10	time 11:24 21:4
281:2,21 283:15	264:19 265:2,10	thousands 340:2	23:8 25:7 27:19
287:10,23 313:25	265:19 268:8	340:14	49:20 57:6 62:4,9
336:8 348:3	270:25 273:7	thread 211:6	86:9 101:14 103:3
things 31:12 54:16	275:4 284:9 295:6	three 45:15 51:4	103:12 109:4,9
63:17 83:6 95:13	298:7 303:7	52:21,25 55:18	110:11 147:12
131:22 135:5	306:21 307:2	62:14 63:16,25	161:23 175:2
136:18 151:22,22	311:15,23 316:3	64:8 73:17 74:15	179:4 181:17
170:8 187:15	319:20 320:16	86:23 109:11	182:22 183:3
257:20 267:17	321:7 322:4	146:20 147:21	185:16 191:2,22
273:13 337:20	323:12 326:8	149:23 154:21	196:12 199:13
think 11:5,12	328:4 329:16	156:25 159:20	200:9 201:7 203:9
13:11 25:14 26:11	331:13 340:24	182:24 192:9	209:2 212:15
27:8 30:15 36:21	345:9 348:22,24	205:5 207:24	219:10,20 225:5
37:25 38:15 39:6	thinking 31:15	208:8 244:9 261:7	226:23 230:25
42:11,15 44:20,21	43:3 107:6 222:9	265:4 271:11	232:12,17 240:7
45:9 48:11 50:25	298:3 312:3	338:8,16	241:25 242:5,5
52:19,25 56:19	third 8:20 25:2,25	threshold 88:12	244:12 245:3
58:2 60:24 62:15	40:4 67:11 75:25	206:14 208:11	254:6 260:4
63:3 64:8 66:18	78:22 79:7,11	209:8,14 331:19	261:15 279:16
73:4,10 74:3	86:21 128:12	335:22,25 337:14	281:7 288:4
75:13 81:15,17	129:18 130:9	342:16 344:15	292:18 294:16
84:9,22 87:9	134:10 148:21	thresholds 206:24	295:6,13,17 298:8
89:17 94:17 96:4	155:4 156:16	207:22 208:20,22	299:21 302:3,7
96:12 106:23	159:2 177:9	214:24 330:11	318:25 320:21
108:18 110:19	196:25 197:3,9	331:18 335:12	322:9,13 329:4,12
111:23 112:7	198:19,24 199:12	threw 345:11	330:14 331:16
115:12 122:13	200:8 201:11	throat 153:24	333:18 350:3,20
123:19,23 128:25	202:7,23 204:23	throw 215:9	350:24 351:9,11
129:15 132:5,13	205:21 220:25	throwing 306:7	353:19
133:14,15 144:15	233:5,6 253:20		

[timeframe - treatment]

Page 61

timeframe 20:23 185:24 353:8	336:23	134:10 137:20	337:3
timeframes 192:14	touches 324:12	142:4 144:20	tracked 97:8
timekeeper 103:13	tout 215:16	145:3 156:8	190:19 245:7
timely 314:14	towns 242:24	172:25 173:6	tracking 86:9
times 49:15 51:6	tpa 70:25 72:21	174:4 177:23	219:19
60:25 201:5	74:12 75:13 76:7	188:23 196:20	traditional 234:8
219:24 320:17	80:21 81:24 82:2	197:17 198:8,10	transaction 67:9
today 12:14 13:6	82:18 96:14 97:3	221:8 223:15	67:10,24 114:14
13:10 15:2 16:2	99:8 128:18	229:5,9,18 233:15	115:17 118:18
16:12,17,23 18:7	130:13 146:25	240:12 251:20	126:20 164:22
18:13 19:11 26:10	147:23 148:17,20	254:17 261:2	195:6 196:19
38:4 39:6 44:7	148:25 149:5,17	280:4,21 284:4,6	198:6 212:13
54:6 148:9 180:8	150:3,17 171:14	284:21,23 285:10	261:11
184:19,23 260:8	171:24 266:23	285:11,19 286:19	transactional 69:4
271:3 278:3	267:3,8,15 269:7	290:21 292:6	transactions 70:7
320:17 322:22	273:16 284:23	296:10 297:23	116:6,9 127:3,13
325:20 345:16	285:8 286:12,18	298:10,22 299:3	141:10 162:9
today's 10:22	287:9,22 289:4,5	300:19 302:10,20	174:3,5
20:15 32:12 66:11	289:18 290:24	303:3,15,22,25	transcript 1:13
351:10	292:2,20 293:18	304:24 305:3,7,16	37:23 353:6,20
told 84:19 94:16	294:6 296:13,19	305:19 306:3,15	355:5,8
211:16 249:5	299:4,24 300:5,6	307:4,15 311:6	transferred
301:11 345:15	302:7 304:6,15	316:10,20	161:12
top 32:22 105:6,25	305:17,24 306:11	tpp's 155:23 302:8	transformed
143:8 157:17,19	307:5,13,25 308:2	tps 42:8 53:8	35:15
161:21 163:23	308:13,14 310:19	57:17 63:5 68:9	transition 108:20
166:10,11,23,24	310:20,21,22	70:19 87:17 92:2	translate 340:17
168:11,22 207:23	315:6,9,16,18	120:8 127:23	transmit 185:18
313:6 320:25	316:10,19	129:4,21 132:6	transmits 307:13
topic 54:3 87:13	tpas 71:18,18	155:3,18 156:3	transmitted 138:2
209:18	86:22 94:25	173:3 178:7,23	254:10 260:20
topics 73:4 145:24	131:14 171:11	179:5 181:12	268:10
232:6	293:24 297:16	205:6 238:12	traurig 3:20
total 20:19 75:24	304:8 311:6	246:2 248:8 252:7	traveling 276:11
103:23 157:7	316:15	252:12,16 258:10	treat 119:6 215:22
159:25 165:16,17	tpp 57:4,9 59:22	302:6 304:19	216:15,16 221:21
207:9 239:6	59:24 65:17 66:15	321:10 324:17	346:11 347:7
251:24 264:22	89:6,8 111:3	tracing 55:20	treated 126:10
294:19 303:15,25	116:5 128:5,6,16	61:12 183:15	256:23 338:21
	128:23 130:4	track 38:10 99:19	treatment 29:23
	132:11,18 133:9	107:11 318:25	92:15 250:16

[treatment - unique]

Page 62

339:11 treats 25:22 tricare 250:9 tried 193:22 258:9 299:10 triggered 121:6 188:19 triggers 190:4 trimming 347:25 true 11:17 34:22 36:7 46:20 83:23 86:7 120:10 132:7 145:9 147:25,25 156:6 185:4 204:21 225:23 231:8 236:25 246:22 284:16 285:6 303:17 308:11,11 315:19 316:15 317:12,13 317:17,21 326:6 352:7 355:8 truth 45:4 341:3 try 11:10 12:13,19 19:13 41:20 51:2 63:18 68:2 73:22 81:18 105:4 107:10 108:6 167:8 175:17 179:20,22 249:4 258:11 287:2 320:15 341:5 345:8 trying 89:13 91:19 91:22 151:19 174:21 213:14 217:21 242:19 275:4 284:2 301:23 311:15 turn 181:14 205:14 260:6	308:15 310:21 twice 96:13 two 22:12 25:13 31:12 39:25 44:21 44:23 45:14,15 48:20 51:7,12 52:24 53:13 54:16 55:15 57:14 62:11 62:14 83:5 84:23 86:14 98:17,19,25 109:6 113:9 136:18 164:12 220:8,12,14 223:9 244:9 262:14 278:12 284:17 290:2 298:9,10 309:18 314:22 339:14 tx 353:15 type 80:19 168:9 246:5,8,9,14,17,25 253:22,23 263:17 263:18,20 310:9 310:11 types 115:16 246:21 253:13,14 253:17 typically 27:17 116:10 117:20 219:6 238:5 239:5 280:21 283:3,12 284:5 287:7 288:21 290:18 296:12 299:23 303:20 327:12 u u 9:17 10:14 uh 246:23 310:3 ulmer 6:4 ultimate 133:9 134:19 226:22	280:21 284:5 286:16 290:17 304:24 306:15 ultimately 78:20 128:7 225:3 236:13 238:7 239:4 314:20 unable 277:25 unavailable 67:18 uncertainty 258:20 uncommon 96:13 212:12 underlying 50:14 50:22 71:3,8 72:16 76:15 83:9 83:21 95:2 137:11 137:20 149:10 150:18 159:12 286:13 306:3 309:4 316:2 346:12 underneath 76:18 underscore 115:12 understand 10:25 11:25 14:3,16 19:3 27:5 29:9 31:11,18 32:18 46:14 48:4 49:5 50:25 57:20 59:10 63:16 83:14 86:2 95:12 105:7 171:6 171:25 175:19 183:12 187:7,22 188:18 193:23 194:25 209:5 211:10 214:3 226:25 234:23 236:22 248:3 260:11 264:25 275:15 291:19	313:4 318:25 330:17 349:22 understanding 34:6 49:11 50:2 56:8 63:8 66:10 66:16 81:20 97:19 104:3,7,10 110:9 168:23 203:23 204:12 207:7 208:7 220:16 228:8,13 254:3 265:18 274:22 329:6 understatement 343:6 understood 10:20 12:9 14:16 17:16 18:3 30:8,13 39:5 160:10 194:22 238:22 undertaken 81:11 107:14 213:3 undertaking 238:18 uniform 67:16 69:3 162:15 172:12 uniformly 129:4 129:11 unintelligible 68:22 82:10 93:16 125:3 137:4 211:7 311:13 union 134:20 287:7,21 288:6,22 290:13 300:13 303:21 unique 272:19 334:12 342:22 344:2
---	--	--	--

[uniquely - vine]

Page 63

uniquely 45:25 70:8 137:16 262:5 262:10 341:16	252:2,25 253:3 254:19 255:2,7,13 260:24 274:25 308:15 312:15,19 312:20 322:2 327:4,11 336:19 348:22	44:10,11 109:22 111:2 118:5,11 121:14 122:19 157:13 166:3 193:14 207:25 225:20,20 332:11 332:16 335:15,16 344:10,21 348:13 348:16 353:4 354:1 355:1	vcds 43:24 44:8 46:7 59:23 60:12 88:3 158:4,14 188:23,24 193:6 203:16 204:5 207:10 210:23 211:20 242:7 302:2,5 347:7
unit 9:4 62:11 109:6,11 182:24 183:5 229:6 232:19 295:19	useful 180:24 212:23 294:3	valuable 162:5 value 46:7 161:18 161:25 241:25 279:19 293:8 294:15	verifiable 306:9 verify 15:12 349:4 353:9
united 1:2 55:18 127:12 187:24	uses 125:6 278:8 311:24 327:20	values 273:5 274:17	veritext 7:19 9:9 353:14,23
universally 112:11 127:10	utility 175:21 utilizing 77:25	valueless 46:4	veritext.com. 353:15
unjust 202:3 203:2 204:13	utter 320:20 utterly 118:4 309:22	vanaskie 199:24 variable 213:17 293:8	versus 80:10 148:12 217:23 242:16
unnecessary 251:14	v	variables 125:23 339:14	veterans 11:10 250:8
unpack 95:4	v 28:6 31:3 124:2 353:4 354:1 355:1	variation 167:18 210:13 211:2,12 212:21 213:10	vett 170:24 327:17
unpaid 141:19	va 257:11	varied 209:25	vial 306:23
unsafe 46:4	vague 64:4 68:14 68:19 74:20 79:15 82:6 88:21 92:8 93:13 110:3 115:2 115:25 120:13 121:19 122:24 124:25 132:22 140:25 144:5 145:19 157:23 162:18 169:18 172:16 175:16 207:3 210:10 212:6 213:25 214:21 226:10 237:15 309:15 315:23 318:17 340:22	varies 293:25 variety 125:11 131:22 308:21	video 9:5 14:6,11 38:7 117:7
unusual 107:12 116:23 288:11	valid 60:20	various 19:16 26:24 39:4 53:6 96:5 208:11 210:22 211:2 213:16 239:3,15 253:11 257:19 261:9 328:25	videoconferenci... 1:18
update 40:21	validated 216:3	vary 294:13	videographer 7:19 9:2,9 62:4,9 109:4 109:9 153:6 182:22 183:3 232:12,17 295:13 295:17 322:9,13 330:2 350:20,24 351:9
updated 178:21	valsartan 1:6 8:16 9:6 40:24 44:9,9	vast 51:14,21 vcd 46:2 157:17 230:25	videotaped 8:10
uploaded 14:4 21:19			view 348:4,4 viewed 80:2 viewing 17:11 vine 6:6
ups 259:5			
usa 3:21 4:5,13			
usage 135:12 335:21			
use 37:18 38:5 64:25 67:17 96:25 108:20 114:19 115:18 118:14 121:13 124:2,17 124:18 125:10 126:22 129:17 137:19 167:11 168:10 177:8 180:16,25 181:5,7 188:12 191:6 214:13 215:5 222:21,22 240:3			

[violations - withdraw]

Page 64

violations 257:2	155:12 156:18	26:2,3 27:12	week 125:11
virtually 70:17	158:15 167:14,15	28:15 41:10 42:3	weeks 21:8 40:2
114:14	168:6 172:22,24	42:4 59:11 63:18	welcome 109:13
visible 185:10	176:10 177:11	63:19 66:25 67:25	went 15:11 102:17
volume 164:12	187:8 193:22	69:9,17 78:2	102:23 169:21
165:17 294:19	198:18,20 201:25	81:19 84:5,6	198:10 215:6
w	205:14,21 210:24	89:19 90:7 93:7	289:3,5
wait 151:16	212:18 216:25	94:11 97:17,22	west 6:14
228:11	220:18 221:23	99:11 101:21	whatnot 11:12
walgreen 3:8	226:21 227:14	112:22 118:9	whatsoever 100:4
walgreens 196:23	237:23 240:9	135:19 137:19	208:24
197:8	246:6,16 247:25	141:22 143:17	whereof 352:14
walk 47:14 335:7	251:15 258:19	145:11 148:11,18	wherewithal
walking 336:20	264:3 269:23	163:15 177:9	314:4
wallace 105:8,12	271:8,21 272:8	196:7 197:14	whichever 238:9
105:13,15	275:22 286:14	202:21 207:20	whiteley 2:4
wallack 7:12	287:10 291:19	216:7,25 243:10	whitney 6:12
walmart 3:8 28:24	292:14,18 294:18	244:5 249:25	wholesale 127:15
29:6	296:7 297:20	257:2 259:25	203:25
walnut 2:16	306:16 307:9	281:19 294:4	wholesaler 119:23
walsh 4:4,8	317:5 318:8 328:6	304:11 307:14,19	156:9,23 185:2,3
want 12:15 15:8	333:25 335:7	310:17 315:3,6,15	185:15,17 189:7
16:7 20:13 36:3	wanted 40:15	316:18 327:3	189:17,19 190:17
37:20 39:21 41:7	61:14 68:7 72:12	333:21 335:24	191:8,13 192:2,3,8
41:20 49:25 52:22	86:12 109:19	337:13 352:12	192:9,10,17,20
57:13,19 60:11	132:14 160:19	ways 67:8 77:3	202:2,6 203:2
62:21 63:11 65:20	165:15 174:14	83:2 224:8 293:13	204:7,22 205:5
66:8 72:18 73:6	344:14 347:9	308:21	wholesalers
75:10,16 76:16	349:7	we've 61:20 70:6,7	154:25 155:16,25
79:20,24 80:14	wanting 313:22	192:2,8 231:22	156:2,12 184:19
81:12,17 82:16	339:24	252:4 259:5 261:9	184:24 188:24
84:9,11,22 85:25	wants 12:16	271:2,23 288:21	204:14 205:7,12
95:6,8,25 99:15	134:25 320:22	295:4 318:3	wide 132:6 324:10
100:22 101:15	warranties 60:5	336:12,13,21,23	wife 195:21 196:3
104:21,22 112:5	washington 5:7	338:16,18,21	wife's 225:25
114:10 123:25	17:6	341:13 347:16	william 7:15
128:3,25 133:23	waste 320:21	349:22	willy 285:15
135:6,14,14 136:6	watch 142:15	wealth 146:3	wise 11:5
136:12 140:21	water 153:17,24	web 259:5	wish 115:11
146:17 149:20	way 10:10 12:3	website 98:24	withdraw 281:18
151:9 153:13	24:16,18 25:20		315:12

[withheld - zoom]

Page 65

withheld 70:3 342:25 withhold 94:9 witness 1:8 8:4 9:15 21:23 22:6 62:2 87:4 90:16 98:8 108:25 116:19,21 117:6 117:12,14 150:19 151:4,9,14,19 152:2 153:10 154:11 167:5 168:14 182:9,16 200:16 201:4 207:4 208:15 218:7 232:4 241:6 259:13 295:11 351:5 352:5,8,14 353:8,10,12,19 witness's 154:19 witnesses 199:24 wonderful 22:9 wondering 281:16 312:25 word 35:6 58:21 66:24 67:7 68:2 96:25 97:21 106:6 106:8 107:4 124:7 133:15 180:24 326:9 words 20:13 59:20 60:11 76:16 95:9 162:14 218:19 229:21 263:12,14 281:9 work 31:11,15,23 78:6 90:3,4 102:11 179:15,17 181:16 196:4 224:14 259:11 270:20 307:18	316:14 317:8 325:21 327:13,15 327:16 340:8,10 workable 182:13 workbook 253:15 worked 78:13 104:19,23 167:10 218:13 230:23 317:12,14,18,19 317:23 318:19 working 22:5 25:11,14 60:15 78:5 231:2 301:17 works 180:14 304:20 worksheet 79:22 80:14 worksheets 71:5 74:13 78:23 79:8 79:10 80:4 81:6,7 81:23 96:6 172:7 273:18 world 88:9 278:7 297:25 310:13 313:8 worries 314:9 worry 223:16 worth 207:24 wound 234:2 wrapped 322:4 writ 99:14 write 138:11 writes 283:18 writing 137:17 215:20 341:15 written 15:18 139:21 155:11 262:12 283:13 302:2 wrong 42:13 103:11,14 190:7	235:22 247:15,17 272:24 282:14,15 wrote 80:15 82:19 172:25	z zalman 7:8 zero 247:12 zhejiang 3:6 9:24 zhp 338:9,18 339:15 341:17 zhp's 335:15 zoom 1:18 14:8 152:15	
		x		
		x 8:2,8 117:21 264:20 336:13,14 xponent 40:9,17 124:5,11,18 125:15 126:6,15 158:7 165:18 166:7 233:11 245:24 246:10 250:24 251:18 253:4 254:19 255:7,13 xyz 216:4		
		y		
		y'all 350:12 yeah 29:4 35:5 43:13 48:16 123:23 135:14 169:3 171:23 172:6 183:20 199:19 240:2 255:21 291:8 314:8 323:13 346:5 year 16:8 141:18 145:7 161:9 172:13 178:10 179:6 190:25 243:13 244:22,23 244:24,25 years 84:22 98:23 99:3,20 146:4 167:24 194:2 244:10 245:10 york 6:15,15		

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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Exhibit 50

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

4 IN RE: VALSARTAN, LOSARTAN, AND) MDL No. 2875
5 IRBESARTAN PRODUCTS LIABILITY)
6 LITIGATION)
7

8 VIDEOTAPED DEPOSITION OF:

9 EDWARD H. KAPLAN, M.D.

10 WEDNESDAY, JANUARY 19, 2022

11 9:14 a.m. Central Standard Time
12

13 TRANSCRIPT of the stenographic notes of the
14 proceedings in the above-entitled matter as taken by and
15 before KELLY A. BRICHETTO, a Certified Court Reporter of
16 the State of Illinois, held at 77 West Wacker Drive,
17 Suite 3100, Chicago, Illinois, on Wednesday, January 19,
18 2022, commencing at approximately 9:14 a.m. pursuant to
19 notice.
20
21
22
23
24

<p style="text-align: right;">Page 2</p> <p>1 A P P E A R A N C E S:</p> <p>2 On behalf of the Plaintiffs:</p> <p>3 RACHEL J. GEMAN (In person)</p> <p>4 LIEFF CABRASER HEIMANN & BERNSTEIN</p> <p>5 250 Hudson Street</p> <p>6 8th Floor</p> <p>7 New York, New York 10013</p> <p>8 (212) 355-9500</p> <p>9 rgeman@lchb.com</p> <p>10</p> <p>11 On behalf of the Plaintiffs:</p> <p>12 NICHOLAS A. MIGLIACCIO (Via Zoom)</p> <p>13 MIGLIACCIO & RATHOD, LLP</p> <p>14 412 H Street NE</p> <p>15 Suite 302</p> <p>16 Washington, D.C. 20002</p> <p>17 (202) 470-3520</p> <p>18 nmigliaccio@classlawdc.com</p> <p>19</p> <p>20 On behalf of the Plaintiffs Executive</p> <p>21 Committee:</p> <p>22 BRETT VAUGHN (Via Zoom)</p> <p>23 HOLLIS LAW FIRM</p> <p>24 8101 College Boulevard</p> <p>Suite 260</p> <p>Overland Park, Kansas 66210</p> <p>(913) 385-5400</p> <p>brett@hollislawfirm.com</p> <p>On behalf of the Brown Plaintiff:</p> <p>DANIEL NIGH (Via Zoom)</p> <p>LEVIN PAPANTONIO THOMAS MITCHELL</p> <p>RAFFERTY & PROCTOR, PA</p> <p>316 South Baylen Street</p> <p>Suite 600</p> <p>Pensacola, Florida 32501</p>	<p style="text-align: right;">Page 4</p> <p>1 On behalf of the Defendant Express</p> <p>2 Scripts:</p> <p>3 JAMES SPUNG (Via Zoom)</p> <p>4 HUSCH BLACKWELL, LLP</p> <p>5 736 Georgia Avenue</p> <p>6 Suite 300</p> <p>7 Chattanooga, Tennessee 37402</p> <p>8 (423) 755-2652</p> <p>9 James.Spung@huschblackwell.com</p> <p>10</p> <p>11 On behalf of the Defendant Sciegen</p> <p>12 Pharmaceuticals:</p> <p>13 GEOFFREY M. COAN (Via Zoom)</p> <p>14 HINSHAW & CULBERTSON, LLP</p> <p>15 53 State Street</p> <p>16 27th Floor</p> <p>17 Boston, Massachusetts 02109</p> <p>18 (617) 213-7045</p> <p>19 GCoan@hinshawlaw.com</p> <p>20 On behalf of the Defendants Zhejiang Huahai</p> <p>21 Pharmaceutical Co., Ltd., Princeton</p> <p>22 Pharmaceutical, Inc. and Solco Healthcare US,</p> <p>23 LLC:</p> <p>24</p> <p>ALYSON LOTMAN (Via Zoom)</p> <p>DUANE MORRIS, LLP</p> <p>30 South 17th Street</p> <p>Philadelphia, Pennsylvania 19103</p> <p>(215) 979-1177</p> <p>ALotman@duanemorris.com</p> <p>On behalf of Mylan Laboratories, Ltd. and</p> <p>Mylan Pharmaceuticals, Inc.:</p> <p>PIETRAGALLO GORDON ALFANO BOSICK &</p> <p>RASPANTI, LLP</p> <p>FRANK STOY (Via Zoom)</p> <p>JASON REEFER</p> <p>301 Grant Street</p> <p>38th Floor</p> <p>One Oxford Centre</p> <p>Pittsburgh, Pennsylvania 15219</p> <p>fhs@pietragallo.com</p>
<p style="text-align: right;">Page 3</p> <p>1 On behalf of the Defendant Camber</p> <p>2 Pharmaceuticals, Inc.:</p> <p>3 ANDREW ALBERTO (Via Zoom)</p> <p>4 LEWIS BRISBOIS</p> <p>5 550 East Swedesford Road</p> <p>6 Suite 270</p> <p>7 Wayne, Pennsylvania 19087</p> <p>8 (215) 977-4058</p> <p>9 Andrew.Alberto@lewisbrisbois.com.</p> <p>10</p> <p>11 On behalf of the Defendant Teva</p> <p>12 Pharmaceuticals USA, Inc.:</p> <p>13 GLENN S. KERNER (In person)</p> <p>14 NILDA ISIDRO (In person)</p> <p>15 GREENBERG TRAURIG, LLP</p> <p>16 One Vanderbilt Avenue</p> <p>17 New York, New York 10017</p> <p>18 (212) 801-9200</p> <p>19 kernerg@gtlaw.com</p> <p>20 isidron@gtlaw.com</p> <p>21</p> <p>22 On behalf of the Defendant Teva</p> <p>23 Pharmaceuticals USA, Inc.:</p> <p>24 KATE WITTLAKE (Via Zoom)</p> <p>GREENBERG TRAURIG, LLP</p> <p>Terminus 200</p> <p>3333 Piedmont Road NE</p> <p>Suite 2500</p> <p>Atlanta, Georgia 30305</p> <p>wittlakek@gtlaw.com</p> <p>On behalf of the Defendant McKesson</p> <p>Corporation:</p> <p>ELLIE NORRIS (Via Zoom)</p> <p>D'LESLI DAVIS (Via Zoom)</p> <p>NORTON ROSE FULBRIGHT, LLP</p> <p>2200 Ross Avenue</p> <p>Suite 3600</p> <p>Dallas, Texas 75201</p> <p>(214) 855-8000</p> <p>ellie.norris@nortonrosefulbright.com</p> <p>dlesli.davis@nortonrosefulbright.com</p>	<p style="text-align: right;">Page 5</p> <p>1 On behalf of the Defendant Amerisource Bergen:</p> <p>2 JEFF D. GEOPPINGER (Via Zoom)</p> <p>3 ULMER & BERNE, LLP</p> <p>4 600 Vine Street</p> <p>5 Suite 2800</p> <p>6 Cincinnati, Ohio 45202</p> <p>7 (513) 698-5000</p> <p>8 jgeoppinger@ulmer.com</p> <p>9</p> <p>10 On behalf of the Defendant CVS Pharmacy, Inc.</p> <p>11 and Rite Aid Corporation:</p> <p>12 MITCHELL CHARCHALIS (Via Zoom)</p> <p>13 BARNES & THORNBURG</p> <p>14 2029 Century Park East</p> <p>15 Suite 300</p> <p>16 Los Angeles, California 90067</p> <p>17 mcharchalis@btlaw.com.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>ALSO PRESENT:</p> <p>BEN PELTA-HELLER, Videographer</p> <p>SCOTT ZIARKO, Videographer</p>

<p style="text-align: right;">Page 6</p> <p>1 TRANSCRIPT INDEX</p> <p>2 APPEARANCES 2</p> <p>3</p> <p>4 INDEX OF EXHIBITS 4</p> <p>5</p> <p>6 EXAMINATION OF EDWARD H. KAPLAN, M.D.</p> <p>7 BY MR. KERNER 11</p> <p>8 BY MS. LOTMAN 107</p> <p>9 BY MR. KERNER 115</p> <p>10 BY MR. GEOPPINGER 121</p> <p>11 BY MS. LOTMAN 126</p> <p>12 BY MS. GEMAN 128</p> <p>13</p> <p>14 REPORTER'S CERTIFICATE 131</p> <p>15</p> <p>16</p> <p>17 EXHIBIT CUSTODY</p> <p>18 COURT REPORTER</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 8</p> <p>1 THE VIDEOGRAPHER: Good morning. We are now</p> <p>2 on the record. My name is Scott Ziarko. I'm the</p> <p>3 videographer representing Veritext Legal Solutions.</p> <p>4 Today's date is January 19th, 2022. The</p> <p>5 time is approximately 9:14 a.m. This deposition is being</p> <p>6 held at 77 West Wacker Drive in Chicago, Illinois as well</p> <p>7 as by Zoom meetings in the matter of In Re: Valsartan,</p> <p>8 Losartan, et al. The name of the witness is Edward H.</p> <p>9 Kaplan, M.D.</p> <p>10 Our court reporter is Kelly Brichetto who</p> <p>11 is also with Veritext Legal Solutions.</p> <p>12 All counsel will be noted in the written</p> <p>13 record.</p> <p>14 Would the court reporter please swear in</p> <p>15 the witness.</p> <p>16 (Witness sworn.)</p> <p>17 You may begin.</p> <p>18 MR. KERNER: Before we get started, Scott, can</p> <p>19 we move the video camera just a touch to get the laptops</p> <p>20 out of the screen since I can't get any closer?</p> <p>21 THE VIDEOGRAPHER: There you go.</p> <p>22 MR. KERNER: Great.</p> <p>23 THE WITNESS: And I have to look at myself.</p> <p>24 MS. GEMAN: I'm sorry. My pen literally just</p>
<p style="text-align: right;">Page 7</p> <p>1 INDEX OF EXHIBITS</p> <p>2 NUMBER DESCRIPTION IDENTIFIED</p> <p>3 Exhibit 1 Notice of Deposition 29</p> <p>4 Exhibit 2 Curriculum Vitae 37</p> <p>5 Exhibit 3 Report of Dr. Kaplan 44</p> <p>6 Exhibit 4 Thumb drive 104</p> <p>7 Exhibit 5 Dr. Kaplan's Invoices 115</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 9</p> <p>1 died. Using the word literally correctly. Is there one</p> <p>2 back here?</p> <p>3 MR. KERNER: We're off to an auspicious</p> <p>4 beginning.</p> <p>5 MS. GEMAN: Indeed. I have others in my room.</p> <p>6 I can go get it.</p> <p>7 MR. KERNER: You need a pen?</p> <p>8 MS. GEMAN: I need a pen.</p> <p>9 MR. KERNER: Do we need this on video?</p> <p>10 THE VIDEOGRAPHER: Want to go off the record?</p> <p>11 MR. KERNER: Yeah, go off the record.</p> <p>12 THE VIDEOGRAPHER: The time is 9:15. We're</p> <p>13 off the record.</p> <p>14 (Discussion had off the</p> <p>15 record.)</p> <p>16 The time is 9:16 a.m. We're back on the</p> <p>17 record. This is media two.</p> <p>18 Will the court reporter please swear in</p> <p>19 the witness.</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

<p style="text-align: right;">Page 10</p> <p>1 (Witness sworn.)</p> <p>2 WHEREUPON:</p> <p>3 EDWARD H. KAPLAN, M.D.,</p> <p>4 called as a witness herein, having been first duly sworn,</p> <p>5 was examined and testified as follows:</p> <p>6 DIRECT EXAMINATION</p> <p>7 BY MR. KERNER:</p> <p>8 Q. Good morning, Dr. Kaplan.</p> <p>9 A. Good morning.</p> <p>10 Q. My name is Glenn Kerner. We met a new</p> <p>11 minutes ago. I am an attorney representing Teva</p> <p>12 Pharmaceuticals in this litigation. I'm here with</p> <p>13 Greenberg Traurig. My partner Nilda Isidro is here as</p> <p>14 well, and I'm going to be asking you a bunch of questions</p> <p>15 this morning, possibly into this afternoon as well about</p> <p>16 your report and the litigation and your opinions in the</p> <p>17 litigation.</p> <p>18 Have you ever had your deposition taken</p> <p>19 before?</p> <p>20 A. Yes.</p> <p>21 Q. How many times?</p> <p>22 A. Three or four times, maybe more. Six times.</p> <p>23 Q. Okay. So then you know how it goes. You're</p> <p>24 under oath, so you have sworn to tell the truth.</p>	<p style="text-align: right;">Page 12</p> <p>1 well.</p> <p>2 A. Okay.</p> <p>3 Q. In the prior depositions that you've taken or</p> <p>4 that you've been deposed, can you tell me when the first</p> <p>5 one was, approximately?</p> <p>6 A. Twenty years ago.</p> <p>7 Q. What kind of case was it?</p> <p>8 A. Malpractice.</p> <p>9 Q. Medical malpractice?</p> <p>10 A. Medical malpractice.</p> <p>11 Q. And were you a party in that case or were you</p> <p>12 a witness?</p> <p>13 A. A witness.</p> <p>14 Q. Were you an expert witness in that case?</p> <p>15 A. I believe I was an expert witness in that</p> <p>16 case.</p> <p>17 Q. Were you paid to testify?</p> <p>18 A. Yes.</p> <p>19 Q. And can you give me some of the details of</p> <p>20 that case?</p> <p>21 A. I can't remember exactly because it's been</p> <p>22 more than ten years since I've done any, but if it's the</p> <p>23 one I'm thinking of then, it was -- it was a woman with</p> <p>24 breast cancer, and I was asked to be an expert for the</p>
<p style="text-align: right;">Page 11</p> <p>1 The way this works obviously is I'm going to</p> <p>2 ask you questions. You're going to answer my questions.</p> <p>3 It will be recorded by both the videographer and the</p> <p>4 stenographer here, so there will be a booklet that has --</p> <p>5 there'll be a transcript that will have all of your</p> <p>6 testimony in it. Do you understand that?</p> <p>7 A. I do. Since this is video and I've not been</p> <p>8 videoed, when I nod my head, that works because in the</p> <p>9 past --</p> <p>10 Q. It doesn't. No, you still need to answer</p> <p>11 verbally so the stenographer can get it.</p> <p>12 A. Got it. Okay.</p> <p>13 Q. But thank you for asking.</p> <p>14 If I ask a question and you're not quite sure</p> <p>15 what I mean, please tell me.</p> <p>16 A. Okay.</p> <p>17 Q. Because if you answer my question, I'm going</p> <p>18 to assume that you understood it, and then it will go</p> <p>19 into the record. We don't want to have any</p> <p>20 misunderstandings. Okay?</p> <p>21 A. Okay.</p> <p>22 Q. Also, I do have a habit sometimes of speaking</p> <p>23 quickly, so I want to warn you in advance of that, so</p> <p>24 let's try not to talk over each other, and I will try as</p>	<p style="text-align: right;">Page 13</p> <p>1 plaintiff.</p> <p>2 Q. And what was the claim in that case?</p> <p>3 A. The claim was -- was that she was</p> <p>4 misdiagnosed. Late diagnosis caused her -- her disease</p> <p>5 to progress and ultimately caused her demise.</p> <p>6 Q. You say that was about 20 years ago you</p> <p>7 think?</p> <p>8 A. I believe it was about 20 years ago.</p> <p>9 Q. Where was that case?</p> <p>10 A. It was in -- it was on the west -- it was on</p> <p>11 the north -- in the northwestern United States.</p> <p>12 Q. Oregon, Washington, something like that?</p> <p>13 A. One of those places.</p> <p>14 Q. You don't remember though?</p> <p>15 A. I will later on I'm sure.</p> <p>16 Q. Okay. Well, if you remember, please let us</p> <p>17 know.</p> <p>18 A. Okay.</p> <p>19 Q. Do you remember the name of the attorney that</p> <p>20 retained you?</p> <p>21 A. I do not.</p> <p>22 Q. Do you remember the name of the firm?</p> <p>23 A. It was an independent person. He was not</p> <p>24 generally a malpractice attorney. That much I remember.</p>

<p style="text-align: right;">Page 14</p> <p>1 I don't remember his name.</p> <p>2 Q. How did he find you?</p> <p>3 A. Through a radiologist friend of mine who was</p> <p>4 asked -- who had done a lot of this and was asked to find</p> <p>5 a medical oncologist that could review the case and</p> <p>6 opine.</p> <p>7 Q. And when you say "review the case," did you</p> <p>8 testify in that case as well?</p> <p>9 A. Yes.</p> <p>10 Q. At deposition, as you said you did?</p> <p>11 A. I testified in court.</p> <p>12 Q. And at deposition, both?</p> <p>13 A. And in deposition.</p> <p>14 Q. And what was the result of that case?</p> <p>15 A. I believe that the case was dropped. I don't</p> <p>16 think it -- it went to court, but I don't think it -- it</p> <p>17 progressed after the time I was in the courtroom.</p> <p>18 Q. When you say it was dropped, do you know what</p> <p>19 you mean by that or is that just a layman's term?</p> <p>20 A. Honestly I --</p> <p>21 MS. GEMAN: I just want to caution you both.</p> <p>22 Please let him finish his question --</p> <p>23 THE WITNESS: Oh.</p> <p>24 MS. GEMAN: -- and likewise.</p>	<p style="text-align: right;">Page 16</p> <p>1 and a medical center I believe or a hospital.</p> <p>2 Q. Do you know what hospital that was or what</p> <p>3 medical center it was?</p> <p>4 A. I don't remember any of the details.</p> <p>5 Q. Okay. Do you remember anything else about</p> <p>6 that particular case?</p> <p>7 A. No, I really don't.</p> <p>8 Q. Okay. When was the next time you had your</p> <p>9 deposition taken?</p> <p>10 A. I really can't remember the times of these.</p> <p>11 I know I have had nothing within the last ten years.</p> <p>12 That's really what I can tell you.</p> <p>13 Q. Okay. I believe you testified that your</p> <p>14 deposition has been taken three or four times. So you</p> <p>15 told us about one.</p> <p>16 A. Right.</p> <p>17 Q. Can you tell us about another one?</p> <p>18 MS. GEMAN: Just objection to the extent it</p> <p>19 misstates testimony.</p> <p>20 MR. KERNER: I'm sorry. I didn't hear it.</p> <p>21 MS. GEMAN: Maybe I should take this off.</p> <p>22 Sorry.</p> <p>23 Objection to the extent it misstates</p> <p>24 testimony.</p>
<p style="text-align: right;">Page 15</p> <p>1 MR. KERNER: I warned you.</p> <p>2 MS. GEMAN: Right, but there was --</p> <p>3 MR. KERNER: Almost.</p> <p>4 MS. GEMAN: No, there was one cutoff of the</p> <p>5 answer. Thank you, both.</p> <p>6 THE WITNESS: Could you repeat the question?</p> <p>7 BY MR. KERNER:</p> <p>8 Q. Sure. You said the case was dropped. Do you</p> <p>9 know what you meant by that?</p> <p>10 A. So I can't remember if that case was -- was</p> <p>11 withdrawn or if it was that they found in favor of the</p> <p>12 defendant. I don't -- and it came to conclusion, but</p> <p>13 after my testimony I didn't have any more interaction. I</p> <p>14 think they had -- the attorney and the client had some</p> <p>15 issues, and I think they may have got other counsel. I</p> <p>16 can't remember all the details.</p> <p>17 Q. Okay. Do you remember the name of the case?</p> <p>18 A. No, I do not.</p> <p>19 Q. Do you remember the name of the defendant --</p> <p>20 A. I do not.</p> <p>21 Q. -- the name of the doctor?</p> <p>22 A. I do not.</p> <p>23 Q. Was it a doctor? Sorry.</p> <p>24 A. It was -- it was a doctor, a group of doctors</p>	<p style="text-align: right;">Page 17</p> <p>1</p> <p>2 BY THE WITNESS:</p> <p>3 A. I had a deposition taken on a patient that I</p> <p>4 was caring for. In fact, this was probably even before</p> <p>5 that case, so it may have been more like 25 years ago.</p> <p>6 And it was a young woman who had gastroesophageal cancer</p> <p>7 or stomach cancer. I can't remember exactly. She was my</p> <p>8 patient for a brief time. It was towards the end of</p> <p>9 her -- of her life, and I was asked -- I was deposed</p> <p>10 to -- as to her condition and to the -- and to the issues</p> <p>11 surrounding her diagnosis. I wasn't opining as to -- as</p> <p>12 to causation or -- or fault. I was just deposed as her</p> <p>13 treating doctor.</p> <p>14 BY MR. KERNER:</p> <p>15 Q. Were you a party in that case?</p> <p>16 A. No.</p> <p>17 Q. You weren't a defendant in that case?</p> <p>18 A. No, I was not.</p> <p>19 Q. So you were just a fact witness?</p> <p>20 A. I was a -- I was a treating physician at the</p> <p>21 time of her death.</p> <p>22 Q. Okay. Do you remember where that case was</p> <p>23 pending?</p> <p>24 A. It was in my office in Skokie.</p>

<p style="text-align: right;">Page 18</p> <p>1 Q. Do you remember the name of the attorney who</p> <p>2 took your deposition?</p> <p>3 A. I do not.</p> <p>4 Q. Do you remember the name of the doctor who</p> <p>5 was the -- was the doctor -- was there a doctor as the</p> <p>6 defendant in the case?</p> <p>7 A. There probably was, but I wasn't -- I wasn't</p> <p>8 really asked to look at any of that. It just was my own</p> <p>9 records and my own treatment of the patient.</p> <p>10 Q. Okay. And again just to be clear, you don't</p> <p>11 remember the name of either party or any of the parties</p> <p>12 in that case?</p> <p>13 A. I do not.</p> <p>14 Q. Any other depositions that you've taken or</p> <p>15 you've had rather?</p> <p>16 A. I've done other depositions. I was deposed</p> <p>17 as an expert reviewing a patient -- it wasn't a -- he</p> <p>18 became a patient but it was a -- a person who was</p> <p>19 claiming exposure to toxins in the workplace, and his</p> <p>20 attorney wanted me to review that and to opine as to</p> <p>21 whether any of the chemicals that he was exposed to could</p> <p>22 have been related to his ultimate development of cancer.</p> <p>23 Q. What kind of cancer did this person have?</p> <p>24 A. I believe it was a soft tissue sarcoma.</p>	<p style="text-align: right;">Page 20</p> <p>1 A. Just that there were some -- some</p> <p>2 benzene-type products that were -- there were some fairly</p> <p>3 toxic substances that are used commonly in -- in cleaning</p> <p>4 solutions in the workplace and at home, but I don't</p> <p>5 remember specifics.</p> <p>6 Q. And I'm sorry if I asked you this already.</p> <p>7 Do you remember the name of any of the parties in that</p> <p>8 case?</p> <p>9 A. I -- I do not.</p> <p>10 Q. What about any of the attorneys that you</p> <p>11 dealt with?</p> <p>12 A. I -- I don't offhand remember the names. If</p> <p>13 I need to look --</p> <p>14 Q. Why do you say it like that?</p> <p>15 A. Because I can't --</p> <p>16 MS. GEMAN: Objection.</p> <p>17 BY THE WITNESS:</p> <p>18 A. I can't remember the names. If I knew that I</p> <p>19 was going to be asked for depositions from before ten</p> <p>20 years, I would have reviewed whatever I could find in my</p> <p>21 old records to -- to get names and dates and places.</p> <p>22 BY MR. KERNER:</p> <p>23 Q. Okay. And so is it your testimony that you</p> <p>24 have some old records either at home or in your office</p>
<p style="text-align: right;">Page 19</p> <p>1 Q. So he was the plaintiff in that case?</p> <p>2 A. He was the -- he was the plaintiff, correct.</p> <p>3 Q. And his attorney asked you to review the</p> <p>4 medical records?</p> <p>5 A. To review the -- to review the medical</p> <p>6 records but also to review the -- the various agents that</p> <p>7 he was exposed to and see if I could find any -- any</p> <p>8 specific link or causation for his ultimate cancer.</p> <p>9 Q. And were you able to?</p> <p>10 A. I was not able to find anything specifically</p> <p>11 linked.</p> <p>12 Q. Do you recall what agents you looked at?</p> <p>13 A. I just recall that there were a lot of --</p> <p>14 of -- of cleaning agents. He was involved in -- in a</p> <p>15 factory that used a lot of solvents that were for -- for</p> <p>16 sterilization and cleaning, and I know I reviewed a lot</p> <p>17 of -- a lot of literature about those agents, and there</p> <p>18 was not any specific -- they were all -- they were all</p> <p>19 pretty much doing all the precautionary things that they</p> <p>20 needed to do in the work -- in the workforce.</p> <p>21 Q. Do you remember what any of the agents were?</p> <p>22 A. I really don't.</p> <p>23 Q. Do you remember any of the classifications of</p> <p>24 any of those agents?</p>	<p style="text-align: right;">Page 21</p> <p>1 that you would have reviewed?</p> <p>2 MS. GEMAN: Objection, misstates the</p> <p>3 testimony.</p> <p>4 BY THE WITNESS:</p> <p>5 A. It's -- could you repeat that, please.</p> <p>6 BY MR. KERNER:</p> <p>7 Q. Sure. Do I understand your testimony to be</p> <p>8 that you have old records that you didn't review from</p> <p>9 prior to ten years ago?</p> <p>10 A. What I'm saying is I could very well have</p> <p>11 something like that laying around since I tend not to</p> <p>12 throw things away, but I haven't looked in certain</p> <p>13 closets in the house for many years, so I would have to</p> <p>14 go looking through those if -- if I was being asked or</p> <p>15 knew I was going to be asked about them.</p> <p>16 Q. Okay. Any other occasions where your</p> <p>17 deposition was taken?</p> <p>18 A. I can't recall any -- any specifics of any</p> <p>19 other depositions, but I know I've been in my office</p> <p>20 deposed before.</p> <p>21 Q. And before this litigation -- you've been</p> <p>22 retained as an expert witness in this litigation;</p> <p>23 correct?</p> <p>24 A. Correct.</p>

<p style="text-align: right;">Page 22</p> <p>1 Q. For the Plaintiffs; correct?</p> <p>2 A. Correct.</p> <p>3 Q. Before this litigation how many times have</p> <p>4 you been retained as an expert witness?</p> <p>5 A. Again, it's been awhile. The last -- last 15</p> <p>6 years was doing nothing in this regard because I was</p> <p>7 taking care of my wife who suffered from breast cancer</p> <p>8 and then ultimately passed away from it, so I was kind of</p> <p>9 out of the picture, and this is the first I've done in a</p> <p>10 long time. But your question was how -- how many times</p> <p>11 was I an expert?</p> <p>12 Q. Correct.</p> <p>13 A. Aside from the case that I just mentioned to</p> <p>14 you, I've been an expert in malpractice cases. Mostly</p> <p>15 record review rather than -- rather than deposition.</p> <p>16 Only a couple times did it actually go to deposition.</p> <p>17 Q. Can you ballpark or estimate for me how many</p> <p>18 times you've been retained as an expert witness either to</p> <p>19 review documents or testify, a number?</p> <p>20 A. In my lifetime?</p> <p>21 Q. Yeah.</p> <p>22 A. Seven or eight times.</p> <p>23 Q. And out of that seven or eight total times,</p> <p>24 how many times do you think it went to deposition?</p>	<p style="text-align: right;">Page 24</p> <p>1 retained as an expert witness in a case that is not a</p> <p>2 medical malpractice case?</p> <p>3 A. Yes.</p> <p>4 Q. And so now you've given us all of the</p> <p>5 depositions that you can remember as you sit here;</p> <p>6 correct?</p> <p>7 A. Correct.</p> <p>8 Q. What's your current professional address?</p> <p>9 A. 9 -- 9631 Gross Point Road, Skokie, Illinois,</p> <p>10 60076.</p> <p>11 Q. Is that an office or a hospital?</p> <p>12 A. It's an office building.</p> <p>13 Q. And you have a practice that's just you?</p> <p>14 What is there?</p> <p>15 A. It's a private practice that includes myself,</p> <p>16 one employed physician and then nurses and physician</p> <p>17 assistant and staff.</p> <p>18 Q. And is it an oncology practice?</p> <p>19 A. Yes, hematology and oncology.</p> <p>20 Q. Tell me what hematology is.</p> <p>21 A. Hematology is the study of -- of</p> <p>22 blood-related disorders.</p> <p>23 Q. So is the practice primarily involved with</p> <p>24 blood cancers?</p>
<p style="text-align: right;">Page 23</p> <p>1 A. Three.</p> <p>2 Q. Okay. In those seven or eight total times</p> <p>3 where you've been retained as an expert witness, how many</p> <p>4 times were you retained for the defendant -- by the</p> <p>5 defendant?</p> <p>6 A. It was about 50/50 percent.</p> <p>7 Q. And in the times that you were retained by</p> <p>8 the defendant, were those defendants physicians?</p> <p>9 A. Yes.</p> <p>10 Q. Were there any occasions where the defendant</p> <p>11 was not a physician, where you were retained by a</p> <p>12 defendant who was not a physician?</p> <p>13 A. I don't believe so.</p> <p>14 Q. And so those would have been malpractice</p> <p>15 cases?</p> <p>16 A. Correct.</p> <p>17 Q. And in the times that you were retained by</p> <p>18 the plaintiff or plaintiffs, putting aside this</p> <p>19 litigation, how many of those were medical malpractice</p> <p>20 cases?</p> <p>21 A. All.</p> <p>22 Q. All?</p> <p>23 A. Um-hum. Yes.</p> <p>24 Q. So is this the first time that you have been</p>	<p style="text-align: right;">Page 25</p> <p>1 A. No.</p> <p>2 Q. What type of cancers does this practice deal</p> <p>3 with? Strike that.</p> <p>4 Hematology and oncology. So does the</p> <p>5 practice deal with more than just cancer?</p> <p>6 A. Yes.</p> <p>7 Q. Does it deal with blood disorders and</p> <p>8 cancers?</p> <p>9 A. Correct.</p> <p>10 Q. What kind of blood disorders does it deal</p> <p>11 with?</p> <p>12 A. Well, aside from the malignant blood</p> <p>13 disorders such as lymphomas, leukemias there are --</p> <p>14 Q. And those are cancers?</p> <p>15 A. Those are cancers. So you want the</p> <p>16 non-cancers?</p> <p>17 Q. Correct.</p> <p>18 A. So that would be -- that would be anemia,</p> <p>19 problems with other blood issues such as low platelet</p> <p>20 count, thrombocytopenia, bone marrow disorders such as</p> <p>21 mild dysplastic syndrome, mild proliferative neoplasms,</p> <p>22 multiple myeloma or plasma self dysplasias which kind of</p> <p>23 is the broad term for -- for that class of illnesses.</p> <p>24 Many things called monoclonal gammopathy of uncertain</p>

Page 26	Page 28
<p>1 significance or MGUS which is pre-cursor to multiple 2 myeloma, problems with just low blood counts in general, 3 sickle cell disease, hemophilia. Those conditions are 4 taken care of by my associate. 5 Q. You anticipated my question. So those blood 6 disorders are dealt with by your associate? 7 A. Correct. 8 Q. And what is his or her name? 9 A. Dr. Marlon Kleinman. Marlon like Brando. 10 Kleinman like Kleinman. 11 Q. And are you the only oncologist in the 12 practice? 13 A. He's also an oncologist. 14 Q. Okay. And in that practice, do you deal 15 exclusively with cancers? 16 A. No. I also do some hematology. We cover for 17 each other. I do have some patients with those 18 conditions I mentioned. 19 Q. Okay. What kind of cancers do you deal with 20 in that practice? 21 A. Pretty much any cancer that there is except 22 mostly I do not take care of acute leukemia. My partner 23 sometimes will. My associate sometimes will, but mostly 24 I take care of everything else. The majority of what I</p>	<p>1 A. Most of the time, yes. 2 Q. By the way, a couple of preliminary questions 3 I should have asked at the beginning. 4 You're not taking any medication that affects 5 your memory today? 6 A. I don't think so. No, I'm not taking any. 7 I'm sorry. 8 Q. And you're capable of testifying fully and 9 truthfully today? 10 A. I better be, yes. 11 Q. That's a yes? 12 A. I've already started. Yes. Yes. 13 Q. I am going to hand you what the court 14 reporter first -- we'll have her mark as Exhibit 1, the 15 Notice of Videotaped Deposition today. 16 (Exhibit No. 1 marked as 17 requested.) 18 MR. KERNER: Rachel, are you looking at the 19 same thing? 20 MS. GEMAN: Yes. 21 BY MR. KERNER: 22 Q. Dr. Kaplan, have you ever seen what's been 23 marked as Exhibit 1 prior to right now? 24 A. Yes.</p>
Page 27	Page 29
<p>1 do though is solid tumors which would include 2 gastrointestinal malignancies, lung cancer, breast 3 cancer, lymphomas, other -- other GI -- oh, I mentioned 4 gastrointestinal cancers. That could be -- that could be 5 anywhere from the esophagus to the stomach to the small 6 bowel to the large bowel, pancreas, gallbladder, biliary 7 tree cancers, liver cancers. 8 Q. Why don't you handle acute leukemia cases? 9 A. Most of the time I believe that that disease 10 requires the facilities of a tertiary care center, and 11 while we may see patients that are also being treated in 12 one of those centers, the majority of the treatment is 13 administered and followed at those centers. 14 Q. Are there any other cancers you'd put into 15 that same category? 16 A. No. 17 Q. What's so unique about acute leukemia that 18 requires that? 19 A. Acute leukemia requires oftentimes inpatient 20 treatments with close monitoring. It could -- it could 21 require bone marrow transplantation and -- and other 22 procedures that we're just not equipped to handle in 23 an -- an in outpatient clinic, outpatient office. 24 Q. So you refer them to another facility?</p>	<p>1 Q. When was the first time you saw it? 2 A. I believe it was about three or four weeks 3 ago. 4 Q. How did you come to see it? 5 A. It was given to me by the attorneys. 6 Q. Which attorney? 7 A. Rachel or one of her colleagues. 8 Q. You don't remember? 9 A. I don't -- I don't remember, no. 10 Q. And you see that it calls for your deposition 11 right here today. So you're here pursuant to this Notice 12 of Deposition; correct? 13 A. Correct. 14 Q. There's also a request for some documents 15 here. Did you review that before today? 16 A. Yeah. 17 Q. On Monday we received some documents. Were 18 the documents that you provided in response to these 19 requests? 20 A. Yes. 21 Q. Any documents in these requests that you 22 didn't provide? 23 A. Not that I know of, no. 24 Q. So everything in these requests you provided</p>

<p style="text-align: right;">Page 30</p> <p>1 on Monday to us; correct?</p> <p>2 MS. GEMAN: Objection to the extent it calls</p> <p>3 for a legal conclusion subject to the responses and</p> <p>4 objections.</p> <p>5 MR. KERNER: Okay. Let me ask it a different</p> <p>6 way.</p> <p>7 BY MR. KERNER:</p> <p>8 Q. Is there anything in this set of requests,</p> <p>9 these 13 requests that you have not provided to us?</p> <p>10 A. I -- I do not believe so.</p> <p>11 Q. So I asked that as a double negative there.</p> <p>12 Have you provided everything that was requested in these</p> <p>13 13 requests --</p> <p>14 MS. GEMAN: Same objection.</p> <p>15 BY MR. KERNER:</p> <p>16 Q. -- that was in your -- that's in your</p> <p>17 possession?</p> <p>18 A. Yes.</p> <p>19 Q. And so request number 6 is for your complete</p> <p>20 and entire file for the case. You provided that?</p> <p>21 A. Yes.</p> <p>22 Q. So there's nothing that you have in</p> <p>23 connection with this case that you haven't provided; is</p> <p>24 that accurate?</p>	<p style="text-align: right;">Page 32</p> <p>1 THE WITNESS: Can I take a break for one</p> <p>2 second --</p> <p>3 MR. KERNER: Yeah, of course.</p> <p>4 THE WITNESS: -- just to ask a question?</p> <p>5 MR. KERNER: Hang on. Hang on. Do you want</p> <p>6 to go off the record? Yeah.</p> <p>7 THE VIDEOGRAPHER: The time is 9:41 a.m. This</p> <p>8 is the end of media two. We're off the record.</p> <p>9 (Discussion had off the</p> <p>10 record.)</p> <p>11 The time is 9:43 a.m. This is the</p> <p>12 beginning of media three. We're back on the record.</p> <p>13 BY MR. KERNER:</p> <p>14 Q. We all set?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Dr. Kaplan, how did you first become</p> <p>17 aware of this litigation?</p> <p>18 A. I was approached by or I was -- I was</p> <p>19 contacted by Expert Institute which is a company that has</p> <p>20 my -- my credentials, my information and they asked me if</p> <p>21 I'd be interested in discussing and reviewing this case</p> <p>22 and introduced me to the -- to the legal team that was</p> <p>23 involved in it.</p> <p>24 Q. Who did they introduce you to?</p>
<p style="text-align: right;">Page 31</p> <p>1 MS. GEMAN: Same objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. There -- there were preliminary drafts which</p> <p>4 I was told I did not need to -- to provide.</p> <p>5 MS. GEMAN: And I'm just going to caution the</p> <p>6 witness not to disclose communications with counsel.</p> <p>7 MR. KERNER: Right.</p> <p>8 BY THE WITNESS:</p> <p>9 A. And communication with counsel.</p> <p>10 BY MR. KERNER:</p> <p>11 Q. I don't want to know about your</p> <p>12 communications with your counsel. Although I believe</p> <p>13 counsel here is Plaintiffs' counsel, so you're actually</p> <p>14 not -- there's not an attorney/client relationship, but</p> <p>15 we don't need to get into that now.</p> <p>16 And I'm not looking for your drafts.</p> <p>17 A. I'm sorry?</p> <p>18 Q. I'm not looking for your drafts today.</p> <p>19 A. Okay.</p> <p>20 Q. Is there anything else that you didn't</p> <p>21 provide that was requested --</p> <p>22 A. No.</p> <p>23 Q. -- in these 13 requests?</p> <p>24 A. No, there isn't.</p>	<p style="text-align: right;">Page 33</p> <p>1 A. To -- to the law firm that -- that I'm --</p> <p>2 that I'm with right now.</p> <p>3 Q. Rachel's law firm?</p> <p>4 A. Rachel's law firm.</p> <p>5 Q. Lieff Cabraser, does that sound familiar?</p> <p>6 A. Yeah, that's one of the law firms.</p> <p>7 Q. What were the other ones?</p> <p>8 A. I don't have the names in front of me.</p> <p>9 Q. What did they tell you that they wanted you</p> <p>10 to do?</p> <p>11 A. They asked if I could review or -- or develop</p> <p>12 a monitoring program for patients that had been shown to</p> <p>13 be exposed to known carcinogens.</p> <p>14 Q. How do you define known carcinogens?</p> <p>15 A. Products that have been identified to</p> <p>16 increase risk of developing malignancies when someone's</p> <p>17 been exposed to them in certain levels.</p> <p>18 Q. And you said the Expert Institute put you in</p> <p>19 contact with Lieff Cabraser?</p> <p>20 A. Correct.</p> <p>21 Q. How did they have your contact information?</p> <p>22 A. I had responded to e-mail requests awhile ago</p> <p>23 for somebody who would be interested -- for people who</p> <p>24 would be interested in being expert witness and sent them</p>

<p style="text-align: right;">Page 34</p> <p>1 my information, my curriculum vitae, so I was on their</p> <p>2 file. I don't remember how long ago I did it, but this</p> <p>3 was the first time I had been contacted by them.</p> <p>4 Q. How long ago did Plaintiffs' lawyers contact</p> <p>5 you?</p> <p>6 A. I believe it was October of 2021, September</p> <p>7 or October.</p> <p>8 Q. Just a few months ago?</p> <p>9 A. Correct. Actually, it may have been a little</p> <p>10 before. It may have been August.</p> <p>11 Q. And they asked you to develop a monitoring</p> <p>12 program for patients exposed to known carcinogens. How</p> <p>13 did you respond?</p> <p>14 MS. GEMAN: Objection to the extent it</p> <p>15 misstates the testimony.</p> <p>16 BY MR. KERNER:</p> <p>17 Q. If that's not what you said, please correct</p> <p>18 it, but I think that's what you said.</p> <p>19 A. Could you repeat the question?</p> <p>20 Q. How did you respond to Plaintiffs' request to</p> <p>21 retain you as an expert?</p> <p>22 A. I agreed to review the information.</p> <p>23 Q. What information did you agree to review?</p> <p>24 A. The testimony of experts that discussed the</p>	<p style="text-align: right;">Page 36</p> <p>1 MR. KERNER: Let's mark this next exhibit. I</p> <p>2 think this is 2; right?</p> <p>3 (Exhibit No. 2 marked as</p> <p>4 requested.)</p> <p>5 BY MR. KERNER:</p> <p>6 Q. Doctor, we've marked as Exhibit -- well,</p> <p>7 we've just handed you Exhibit 2. Can you tell me what</p> <p>8 that is?</p> <p>9 A. This is a copy of my curriculum vitae.</p> <p>10 Q. And can you tell me if that's your most</p> <p>11 current CV?</p> <p>12 A. I believe it is.</p> <p>13 Q. And this was attached to your report?</p> <p>14 A. Yes.</p> <p>15 MR. KERNER: How do we want to handle exhibits</p> <p>16 with the Zoom? I realize we didn't do that for the</p> <p>17 Notice of Deposition. Do we want to get the CV up on the</p> <p>18 Zoom for folks that are remote?</p> <p>19 MS. ISIDRO: Yes. That's in progress.</p> <p>20 MR. KERNER: Great.</p> <p>21 BY MR. KERNER:</p> <p>22 Q. So, Doctor, let's go backwards. Let's start</p> <p>23 with your medical school. Where did you go and when did</p> <p>24 you graduate?</p>
<p style="text-align: right;">Page 35</p> <p>1 risks associated with nitrosamine products from tainted</p> <p>2 Valsartan.</p> <p>3 Q. Which specific expert's testimony did you</p> <p>4 review?</p> <p>5 A. I have it in my --</p> <p>6 Q. In your report?</p> <p>7 A. -- report.</p> <p>8 Q. So the experts' testimony that you reviewed</p> <p>9 are the experts that you've identified in your report?</p> <p>10 A. Correct.</p> <p>11 Q. Any others?</p> <p>12 A. No.</p> <p>13 Q. And in addition to reviewing their testimony,</p> <p>14 did you review anything else?</p> <p>15 A. At that time?</p> <p>16 Q. Yes.</p> <p>17 A. No.</p> <p>18 Q. In preparing your report, did you review</p> <p>19 anything else or just that testimony?</p> <p>20 A. No. In preparing my report, I reviewed</p> <p>21 various articles and resources.</p> <p>22 Q. And are those articles and resources attached</p> <p>23 to your report?</p> <p>24 A. Yes, they are.</p>	<p style="text-align: right;">Page 37</p> <p>1 A. I went to Loyola University Medical Center in</p> <p>2 Maywood, Illinois, and I graduated in 1982.</p> <p>3 Q. Did you have a residency after that?</p> <p>4 A. I had a residency -- internship and residency</p> <p>5 at Northwestern University in Chicago.</p> <p>6 Q. What did you do after the internship and the</p> <p>7 residency?</p> <p>8 A. I went on to a hematology/oncology fellowship</p> <p>9 at Northwestern University in Chicago.</p> <p>10 Q. And the residency was in internal medicine;</p> <p>11 correct?</p> <p>12 A. Correct.</p> <p>13 Q. And the fellowship was you said at</p> <p>14 Northwestern --</p> <p>15 A. Yes.</p> <p>16 Q. -- in hematology and oncology?</p> <p>17 That was according to your CV from 1983 to</p> <p>18 1985?</p> <p>19 A. The fellowship was 1985 to 1988.</p> <p>20 Q. Ahh, okay. And so after the fellowship, when</p> <p>21 it concluded in 1988, what did you do next?</p> <p>22 A. I joined the faculty at Rush University in</p> <p>23 Chicago.</p> <p>24 Q. In what role?</p>

Page 38	Page 40
<p>1 A. As a medical -- as a hematology/oncology</p> <p>2 attending physician.</p> <p>3 Q. Is that still your role there?</p> <p>4 A. No. I was -- I was full-time there for five</p> <p>5 years and then went into private practice after that but</p> <p>6 maintained my -- my teaching role at Rush University and</p> <p>7 am still an Assistant Professor of Medicine at Rush</p> <p>8 University.</p> <p>9 Q. And you've been an Assistant Professor of</p> <p>10 Medicine at Rush since 1988?</p> <p>11 A. Correct.</p> <p>12 Q. What do your responsibilities at Rush entail</p> <p>13 now?</p> <p>14 A. My responsibilities at Rush would entail</p> <p>15 allowing residents and students to rotate through our</p> <p>16 office to acquire clinical experience. There's been</p> <p>17 teaching roles. There's been clinical clerkships, but I</p> <p>18 have had no responsibilities on the campus for a number</p> <p>19 of years.</p> <p>20 Q. When you say "allow them to rotate," what do</p> <p>21 you mean by that?</p> <p>22 A. Providing them a rotation, a clinical</p> <p>23 rotation in our -- in our -- in our practice for the --</p> <p>24 for the residents or -- or fellows that wish to have a</p>	<p>1 Q. And the invited lectures and presentations --</p> <p>2 A. Concerning?</p> <p>3 Q. -- any of them concerning NDMA or NDEA?</p> <p>4 A. No.</p> <p>5 Q. Or Valsartan?</p> <p>6 A. No.</p> <p>7 Q. Or the Valsartan drugs?</p> <p>8 A. Correct.</p> <p>9 Q. Other than the report that the Plaintiffs'</p> <p>10 attorneys asked you to draft and develop in this</p> <p>11 litigation have you ever written or presented or spoke</p> <p>12 outside the litigation on NDMA, NDEA or any of the</p> <p>13 Valsartan drugs?</p> <p>14 A. No, I haven't.</p> <p>15 Q. Since the litigation began other than your</p> <p>16 report, have you written or presented or spoken on NDMA,</p> <p>17 NDEA or any of the Valsartan drugs?</p> <p>18 A. No, I haven't.</p> <p>19 Q. So it's limited to this report; correct?</p> <p>20 A. Yes.</p> <p>21 Q. When the Plaintiffs asked -- Plaintiffs'</p> <p>22 counsel -- excuse me. Okay. I misspoke earlier.</p> <p>23 When Plaintiffs' counsel asked you to develop</p> <p>24 a monitoring program, did they give you any more guidance</p>
Page 39	Page 41
<p>1 community oncology experience.</p> <p>2 Q. Do you supervise them?</p> <p>3 A. Yes.</p> <p>4 Q. Do you teach them?</p> <p>5 A. Yes.</p> <p>6 Q. What do you teach them?</p> <p>7 A. Teach them clinical -- clinical oncology.</p> <p>8 For -- for ten years -- until 1995 I was assigned as</p> <p>9 the -- the Chairman of Oncology at NorthShore</p> <p>10 University -- at -- sorry -- at Rush NorthShore in</p> <p>11 Skokie. That was part of my role at Rush. After I left</p> <p>12 full-time faculty at Rush I maintained that role until</p> <p>13 the hospital was sold to NorthShore University.</p> <p>14 Q. Okay. Now, in looking at your CV, there are</p> <p>15 a bunch of publications, and I see there's some patents</p> <p>16 as well and some abstracts and invited lectures and</p> <p>17 presentations. How many of these publications dealt with</p> <p>18 NDMA or NDEA?</p> <p>19 A. None.</p> <p>20 Q. How about Valsartan or any of the Valsartan</p> <p>21 drugs?</p> <p>22 A. None.</p> <p>23 Q. What about the abstracts?</p> <p>24 A. None.</p>	<p>1 or instruction as to how to do it?</p> <p>2 A. No.</p> <p>3 Q. What they were looking for?</p> <p>4 A. No.</p> <p>5 Q. They just said develop a program and --</p> <p>6 A. They -- they --</p> <p>7 MR. KERNER: Go ahead. I'm sorry.</p> <p>8 MS. GEMAN: I just want to caution you. You</p> <p>9 can speak to any facts or assumptions provided, but I</p> <p>10 don't -- I don't see Mr. Kerner is asking beyond that.</p> <p>11 MR. KERNER: I think I heard you.</p> <p>12 MS. GEMAN: Sorry.</p> <p>13 MR. KERNER: That's okay. I know.</p> <p>14 THE WITNESS: Could you repeat the question?</p> <p>15 MR. KERNER: I'm not sure that I could.</p> <p>16 BY MR. KERNER:</p> <p>17 Q. When Plaintiffs' counsel asked you to develop</p> <p>18 a monitoring program, did they give you any instruction</p> <p>19 or guidance as to what they wanted?</p> <p>20 MS. GEMAN: Objection, asked and answered.</p> <p>21 BY THE WITNESS:</p> <p>22 A. They advised me as to the -- the details of</p> <p>23 the case and asked if I felt that I could present a</p> <p>24 monitoring program for the group of patients that were</p>

<p style="text-align: right;">Page 42</p> <p>1 identified as being at high risk for developing a group 2 of cancers. 3 BY MR. KERNER: 4 Q. And when you said they gave you the details 5 of the case, what did they tell you were the details? 6 A. The details were that it had been established 7 by their expert reviewers and by the history of the 8 litigation that the Valsartan tainted materials when 9 exposed in certain amounts to patients was considered a 10 risk for the patients ultimately developing malignancies, 11 that these were carcinogens and then the levels that they 12 were exposed to, that they were at risk. And part of 13 this kind of evaluation or legal review does allow for 14 monitoring, medical monitoring in situation, and my 15 experience with patient care and patient -- patient -- 16 review patient care would allow me to develop an 17 appropriate monitoring program in that situation. 18 Q. Okay. You said -- and I don't want to 19 misstate your testimony. I'm trying to remember what you 20 just said -- that their expert reviewers established that 21 Valsartan was considered an increased risk. Did you do 22 any independent analysis as to Valsartan or NDMA other 23 than what their other experts had established? 24 A. So my understanding, it wasn't Valsartan that</p>	<p style="text-align: right;">Page 44</p> <p>1 address. One of the attorneys -- one of the attorneys 2 for the Plaintiff. 3 Q. Somebody told you to address it to 4 Mr. Slater? 5 A. Correct. 6 Q. Do you remember who told you that? 7 A. No. 8 Q. Okay. You said a moment ago that -- I think 9 you said a moment ago that you were asked to develop a 10 medical monitoring program, and then I think you said the 11 legal review allows for medical monitoring in this case. 12 That's what you said; correct? 13 A. I think that's what my terminology was, yes. 14 Q. Prior to this case have you ever created a 15 medical monitoring program? 16 A. I've not developed a public medical 17 monitoring program but I've been involved in my own 18 patient care of -- of developing monitoring programs. 19 Q. What do those monitoring programs consist of? 20 And what do you mean by monitoring programs for your 21 patients? 22 A. So to get into detail, my experience in my 23 practice includes patients that have high risk of 24 developing cancer usually because of genetic</p>
<p style="text-align: right;">Page 43</p> <p>1 was putting the patients at risk. It was the Valsartan 2 that was manufactured in a way that had been tainted with 3 these dangerous substances. I did not do independent 4 review. That's not what I was asked to do. I was asked 5 to just develop a monitoring program. 6 Q. Okay. And -- and to your point, you don't 7 have any criticism of the drug Valsartan; correct? 8 A. Correct. 9 Q. And you're relying on the Plaintiffs' other 10 experts for their analysis of any carcinogenic effect of 11 the, as I think you put it, the tainted Valsartan; 12 correct? 13 A. Correct. 14 Q. Okay. Let's get to what we're going to mark 15 as Exhibit 3. 16 (Exhibit No. 3 marked as 17 requested.) 18 The Zoom folks be aware of that as well. 19 Okay. Doctor, can you tell me what Exhibit 3 20 is? 21 A. This was the report that I provided to the -- 22 to -- to Mr. Slater and the other attorneys. 23 Q. Who's Mr. Slater? 24 A. Mr. Slater is the one I was told to -- to</p>	<p style="text-align: right;">Page 45</p> <p>1 abnormalities such as BRCA gene or Lynch syndrome. I 2 follow patients and families of patients that haven't 3 developed cancer that -- but do carry these genetic 4 abnormalities and monitor them for malignancies. 5 Q. How do you do that? 6 A. Various ways depending on the situation. 7 Q. Can you explain that to me? 8 A. Certainly. In -- for example, in Lynch 9 syndrome which is genetic abnormality that predisposes to 10 gastrointestinal malignancies, I will follow the patients 11 twice a year. The ones that do not have cancer, have not 12 developed cancer we'll follow them twice a year with 13 clinical exam, routine exams that include physical exam, 14 history and basic blood analysis. I will assure that 15 they're getting annual colonoscopies because of the high 16 risk of developing polyposis and ultimately 17 gastrointest -- colonic carcinoma. I will also follow 18 them for development of uterine cancer by referring them 19 to gynecologist by ordering radiographic studies such as 20 ultrasounds, occasionally CAT scans. 21 Q. Let me interrupt you for one second, sir. 22 For Lynch syndrome, one of the things you just said I 23 think is that you -- you have them have an annual 24 colonoscopy --</p>

<p style="text-align: right;">Page 46</p> <p>1 A. Correct.</p> <p>2 Q. -- correct?</p> <p>3 Do you have all of your patients who are --</p> <p>4 is it -- are they -- do they have Lynch syndrome or are</p> <p>5 they susceptible to Lynch syndrome?</p> <p>6 A. No. These are patients --</p> <p>7 MS. GEMAN: I just want to --</p> <p>8 BY THE WITNESS:</p> <p>9 A. -- with --</p> <p>10 MS. GEMAN: I just want to object. The</p> <p>11 witness was not done answering the previous question, so</p> <p>12 I just want to make sure the record's clear that that</p> <p>13 wasn't an answer -- a complete answer.</p> <p>14 MR. KERNER: Sure, and we'll come back to that</p> <p>15 in a second. I appreciate that.</p> <p>16 MS. GEMAN: Yeah.</p> <p>17 BY MR. KERNER:</p> <p>18 Q. Lynch syndrome.</p> <p>19 A. Thank you. Patients that have identified</p> <p>20 Lynch syndrome, it's recommended that they get annual</p> <p>21 colonoscopies.</p> <p>22 Q. Are there patients who perhaps for other</p> <p>23 reasons, whether it's other history or comorbidities or</p> <p>24 something, might not be -- might not be appropriate to</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. So you don't know if it's a national</p> <p>2 statistic or a worldwide statistic? It's just a Kaplan</p> <p>3 statistic of less than .1 percent of perforated colons?</p> <p>4 A. As I said, I was guessing it was either 1</p> <p>5 percent or maybe even .1 percent. I was not opining as</p> <p>6 to the exact statistic. I know that there's literature</p> <p>7 that could answer that question.</p> <p>8 Q. So to be fair, as you sit here right now, you</p> <p>9 don't really know how many -- what the percentage is of</p> <p>10 colonoscopy patients who have perforated colons during</p> <p>11 the procedure?</p> <p>12 A. I know it's very rare.</p> <p>13 Q. But you don't know what you mean by "very</p> <p>14 rare"?</p> <p>15 MS. GEMAN: Objection.</p> <p>16 BY MR. KERNER:</p> <p>17 Q. What do you mean by "very rare?"</p> <p>18 A. I've taken care of over 1,000 patients that</p> <p>19 have had colonoscopies, probably more like 3,000 patients</p> <p>20 in my career that have had colonoscopies and I've seen 2</p> <p>21 perforations.</p> <p>22 Q. But, again, as a good doctor who cares about</p> <p>23 his patients, you consider that as to whether a patient</p> <p>24 should have an annual colonoscopy; correct?</p>
<p style="text-align: right;">Page 47</p> <p>1 have an annual colonoscopy?</p> <p>2 A. Yes.</p> <p>3 Q. Can you give me an example or two of a type</p> <p>4 of patient where you wouldn't -- with Lynch syndrome</p> <p>5 where you wouldn't provide an annual colonoscopy for?</p> <p>6 A. An elderly patient with severe cardiovascular</p> <p>7 disease, somebody that had a colonoscopy and had a</p> <p>8 complication such as a perforation, someone that just</p> <p>9 refuses.</p> <p>10 Q. How common are perforations during</p> <p>11 colonoscopies?</p> <p>12 A. Very uncommon.</p> <p>13 Q. I'm sorry?</p> <p>14 A. Very uncommon. I believe less than 1</p> <p>15 percent. I believe less than .1 percent, but I don't</p> <p>16 know exactly.</p> <p>17 Q. Less than .1 percent?</p> <p>18 A. I believe so, but I don't know exactly.</p> <p>19 Q. You don't happen to have any data or support</p> <p>20 that you can cite to me for that figure, do you?</p> <p>21 A. No, I don't.</p> <p>22 Q. Do you know where that figure comes from?</p> <p>23 A. Just from my own experience in -- in</p> <p>24 practice.</p>	<p style="text-align: right;">Page 49</p> <p>1 A. Could you repeat that? I just got stopped at</p> <p>2 the "good doctor" because I'm glad you said that.</p> <p>3 Q. Yeah. Strike that.</p> <p>4 As a doctor who's concerned about his</p> <p>5 patients, I think you testified a few minutes ago that</p> <p>6 one of the reasons why you may not recommend an annual</p> <p>7 colonoscopy is if it's an elderly patient, the risk</p> <p>8 of -- the risk of a perforated colon and some other</p> <p>9 possible reasons?</p> <p>10 A. What I said was if someone had had a</p> <p>11 perforation in their colon I would not recommend going</p> <p>12 back necessarily with a colonoscopy.</p> <p>13 Q. Any other reasons why you might not recommend</p> <p>14 the annual colonoscopy for a Lynch syndrome patient?</p> <p>15 A. Aside from comorbidities, risk of problems</p> <p>16 related to anesthesia, I can't think of any other reason</p> <p>17 I would not recommend an annual colonoscopy.</p> <p>18 Q. So there are some risks that are -- that come</p> <p>19 along with a colonoscopy; correct?</p> <p>20 A. Correct.</p> <p>21 Q. And so what you do with your patients with</p> <p>22 Lynch syndrome is you weigh the risks versus the</p> <p>23 benefits?</p> <p>24 A. Correct.</p>

<p style="text-align: right;">Page 50</p> <p>1 Q. And in your medical judgment, as a treating 2 physician of those patients, you make the recommendation 3 one way or the other; correct? 4 A. Correct. 5 Q. One of the things I think you said is that -- 6 I'll let you finish taking your notes. 7 A. I was saying you said I was a good doctor. 8 Sorry. 9 Q. One of the things I think you said with 10 respect to Lynch syndrome is that it is recommended that 11 they have annual colonoscopies? 12 A. Correct. 13 Q. By whom? 14 A. By I believe a number of agencies. The NCCN 15 has it in their guidelines. 16 Q. What's the NCCN? 17 A. The NCCN is the National -- I knew you were 18 going to ask me this. I can't remember what it stands 19 for. It's a -- it's a -- it's an organization that's -- 20 that reviews every malignancy class and has experts from 21 around the country and even around the world will meet 22 regularly and create algorithms for how many conditions 23 are treated but also for screening and for -- and for 24 monitoring.</p>	<p style="text-align: right;">Page 52</p> <p>1 A. Well, of course, the patient. 2 Q. What do you look at with respect to the 3 patient? 4 A. This is when deciding on treatment for the 5 patient? 6 Q. Yes. 7 A. The -- the details of the patient's specific 8 situation, the disease itself, of course, the performance 9 status of the patient which is a measure of how 10 functional and how sick they are, the comorbidities, 11 patient's desires themselves. 12 Q. Family history? 13 A. In deciding on treatment, usually not. 14 Q. Would you take family history into account in 15 determining whether a certain procedure is appropriate 16 and may be more likely to be appropriate because of 17 family history? 18 A. Could you explain that question? 19 Q. Sure. For colonoscopy would you be more 20 likely to think a colonoscopy is appropriate annually 21 because they have Lynch syndrome? 22 A. Yes. I already mentioned that Lynch -- 23 Q. Right. 24 A. -- syndrome, but Lynch syndrome, although</p>
<p style="text-align: right;">Page 51</p> <p>1 Q. Is it the National Comprehensive Cancer 2 Network? 3 A. That's it. Thank you. 4 Q. And they develop screening protocols, is that 5 what -- 6 A. They have recommendations in their algorithm 7 for what should be done with patients. 8 Q. They're pretty well-regarded; right? 9 A. Yes. 10 Q. Do you generally follow their guidelines? 11 A. Generally. 12 Q. Are there specific guidelines that you don't 13 follow? 14 A. On an individual basis I will review -- and 15 this is usually for treating patients. I will review 16 their recommendations, and they usually have more than 17 one suggested direction, but we use them to -- to help 18 decide on appropriate treatments for patients. 19 Q. What else do you use to decide on appropriate 20 treatments for patients? 21 A. My own experience, the literature, any 22 investigational trials that we're involved in or that 23 we've reviewed. 24 Q. What about the patient him or herself?</p>	<p style="text-align: right;">Page 53</p> <p>1 it's linked to family history, it's specific to that 2 patient because they've been diagnosed with carrying the 3 gene. 4 Q. Fair. What about a patient who has a first 5 degree relative who has had colon cancer? 6 A. That would -- 7 MS. GEMAN: Objection, vague. 8 BY THE WITNESS: 9 A. That would factor into my -- my assessment of 10 the patient's own risk and the need for that patient to 11 undergo genetic testing but wouldn't necessarily -- 12 wouldn't necessarily at all factor into my decision about 13 putting them through colonoscopy or any other test. It's 14 part of the general evaluation of the patient. 15 BY MR. KERNER: 16 Q. Okay. So in terms of treatment which is what 17 you're talking about? 18 A. Correct. 19 Q. You mentioned comorbidities. You mentioned 20 the patient's desires. You mentioned the performance 21 status of the patient. What do you mean by that? 22 A. So in part of the evaluation of a patient, 23 and especially oncology patients that are going through 24 treatments or are anticipating going through treatments,</p>

<p style="text-align: right;">Page 54</p> <p>1 one of the ways to quantitate how the patient is doing is</p> <p>2 using a -- a table, a gauge based on a number of factors</p> <p>3 to determine how fit they are. There's two accepted</p> <p>4 methods. One is called the ECOG, Eastern Cooperative</p> <p>5 Oncology Group Performance Status, and the other is the</p> <p>6 Karnofsky Performance Status. We usually use the ECOG</p> <p>7 criteria. It's pretty straightforward. It's from zero</p> <p>8 to four. Zero is somebody that's totally asymptomatic</p> <p>9 and performing their normal day-to-day activities. One</p> <p>10 is somebody that's functional and doing everything but</p> <p>11 probably at better than 50 percent of their normal</p> <p>12 activities. Two is -- two and three and four are then</p> <p>13 progressively worse, with four being near death.</p> <p>14 Q. And so that will help guide you with the</p> <p>15 treatment that you're going to provide for the patient;</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. One of the things?</p> <p>19 A. Correct.</p> <p>20 Q. And is that something that NCCN also -- it's</p> <p>21 also part of their guidelines?</p> <p>22 A. I'm not exactly sure how -- how they would</p> <p>23 use it in their guidelines. I believe they do. I think</p> <p>24 there's many studies suggesting that someone that is a</p>	<p style="text-align: right;">Page 56</p> <p>1 cancer recurrence." We've talked a little bit about that</p> <p>2 already; correct?</p> <p>3 A. Yes.</p> <p>4 Q. Anything about the screening programs that</p> <p>5 you said you designed for your patients that you haven't</p> <p>6 told us yet?</p> <p>7 MS. GEMAN: Objection.</p> <p>8 BY THE WITNESS:</p> <p>9 A. We didn't talk about patients that have been</p> <p>10 treated for cancer, and so they're in a unique group</p> <p>11 that's going to be monitored a little differently than a</p> <p>12 healthy person that walks in that needs to be evaluated</p> <p>13 with cancer.</p> <p>14 BY MR. KERNER:</p> <p>15 Q. And that's where you're talking about cancer</p> <p>16 recurrence; correct?</p> <p>17 A. Correct.</p> <p>18 Q. So tell me what the difference is in your</p> <p>19 view with a patient who you're screening for a risk of</p> <p>20 cancer versus a cancer recurrence. Because I would</p> <p>21 assume, I shouldn't, but that somebody you're treating</p> <p>22 for cancer recurrence you might be a little bit more</p> <p>23 aggressive in terms of your -- in terms of your</p> <p>24 screening?</p>
<p style="text-align: right;">Page 55</p> <p>1 performance status of three or worse is not likely to</p> <p>2 benefit from some of the aggressive treatments we might</p> <p>3 otherwise use that's been established. Although a lot of</p> <p>4 that's changing because of new therapies that have come</p> <p>5 out that are even appropriate for very ill patients.</p> <p>6 Q. Okay. Let's take a look at your report.</p> <p>7 A. Okay.</p> <p>8 Q. And we've marked that as Exhibit 3.</p> <p>9 You want to get that back up for the Zoom?</p> <p>10 Okay. Did you draft this report?</p> <p>11 A. Yes.</p> <p>12 Q. Did Plaintiffs' counsel provide any input in</p> <p>13 the report?</p> <p>14 A. Only typographically.</p> <p>15 Q. And you mean literally typos --</p> <p>16 A. Correct.</p> <p>17 Q. -- if there were errors? That's it?</p> <p>18 A. Yeah.</p> <p>19 Q. Nothing else?</p> <p>20 A. I don't believe so, no.</p> <p>21 Q. Okay. Let's go -- in the first paragraph,</p> <p>22 "Expert Background Qualifications," you mention that you</p> <p>23 "designed screening programs for the patient I treat and</p> <p>24 frequently monitor patients at high risk for cancer or</p>	<p style="text-align: right;">Page 57</p> <p>1 A. I'm not sure what aggressive --</p> <p>2 Q. Strike that.</p> <p>3 A. -- means. From where?</p> <p>4 Q. Tell me -- tell me how your screening is</p> <p>5 different for patients at high risk for cancer versus</p> <p>6 patients with cancer recurrence.</p> <p>7 A. All of the patients will receive general</p> <p>8 evaluation. By that I mean history, a physical exam,</p> <p>9 basic laboratory studies. Patients with specific</p> <p>10 conditions will have blood tests that are designed</p> <p>11 specifically for that cancer. For example, ovarian</p> <p>12 cancer with a tumor marker called CA125 or pancreatic</p> <p>13 cancer with a tumor marker called CA929, I won't do that</p> <p>14 on a patient who didn't have the history of pancreatic</p> <p>15 cancer necessarily.</p> <p>16 Q. Why not?</p> <p>17 A. Because that test is designed specifically</p> <p>18 to -- to detect pancreatic cancer recurrence.</p> <p>19 Q. Okay.</p> <p>20 A. The other thing might be, as you alluded to,</p> <p>21 more aggressive procedures, so that might include doing</p> <p>22 CAT scans more frequently. Somebody that's had lung</p> <p>23 cancer that's been treated that had surgery but is high</p> <p>24 risk for recurrence will get CAT scans frequently.</p>

<p style="text-align: right;">Page 58</p> <p>1 Q. What do you mean "frequently"?</p> <p>2 A. I mean depending on where they are from their</p> <p>3 treatment and what their situation is and what their</p> <p>4 symptoms are. It could be -- it could be every three</p> <p>5 months, every four months, every six months, every year.</p> <p>6 It's not set in stone. It depends on the patient.</p> <p>7 Q. And that would be true for patients who you</p> <p>8 believe are at high risk for cancer. It depends on the</p> <p>9 patient in terms of what the screening will be; correct?</p> <p>10 A. Well, not necessarily. Patients that are at</p> <p>11 high risk for cancer that have no other symptoms or</p> <p>12 problems I will have a specific general monitoring scheme</p> <p>13 in mind which is exactly what this is all about. While</p> <p>14 as patients that have had a specific problem or have a</p> <p>15 symptom will necessitate getting additional testing done.</p> <p>16 Q. Okay. So there are -- at least in this first</p> <p>17 section of your report, there are screening programs for</p> <p>18 patients at high risk for cancer and for cancer</p> <p>19 recurrence. Do you make any other distinctions between</p> <p>20 asymptomatic or symptomatic patients or patients with</p> <p>21 specific exposures?</p> <p>22 MS. GEMAN: Objection.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I'm not sure I understand the question.</p>	<p style="text-align: right;">Page 60</p> <p>1 or could be many different types, there's going to be</p> <p>2 general screening protocols that I'll provide. An</p> <p>3 example would be someone with tobacco exposure's not just</p> <p>4 at risk for one cancer, so it would be a number of -- of</p> <p>5 procedures that are done to monitor them.</p> <p>6 MR. KERNER: Okay. Let's take a five-minute</p> <p>7 break if we can. We've been at it a little over an hour.</p> <p>8 THE VIDEOGRAPHER: The time is now 10:21 a.m.</p> <p>9 This is the end of media three. We're off the record.</p> <p>10 (WHEREUPON, a break was</p> <p>11 taken.)</p> <p>12 The time is now 10:39 a.m. This is the</p> <p>13 beginning of media four. We're back on the record.</p> <p>14 BY MR. KERNER:</p> <p>15 Q. Okay, Doctor. A few more questions</p> <p>16 obviously.</p> <p>17 We're talking about paragraph 1 in your</p> <p>18 report, and I want to talk about your practice. You</p> <p>19 mentioned that you designed screening programs for</p> <p>20 certain patients. I think you testified that you have</p> <p>21 designed screening programs for patients with genetic</p> <p>22 predisposition such as BRCA or Lynch syndrome; is that</p> <p>23 correct?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 59</p> <p>1</p> <p>2 BY MR. KERNER:</p> <p>3 Q. Okay. In your practice, when you're</p> <p>4 screening your patients, do you make any distinctions if</p> <p>5 a patient is symptomatic or asymptomatic in terms of the</p> <p>6 screening?</p> <p>7 A. The basic screening there will be no</p> <p>8 distinction. If someone's symptomatic, that goes on from</p> <p>9 screening to evaluation. So somebody, for example, that</p> <p>10 has a cough is going to have something done more to</p> <p>11 evaluate that than someone that comes in without any</p> <p>12 symptoms, but there's a basic screening that would be</p> <p>13 provided to anybody that I identified as being at risk.</p> <p>14 Q. At risk for what?</p> <p>15 A. Developing cancer.</p> <p>16 Q. Which type of cancer?</p> <p>17 A. All -- all -- I mean it depends on what I'm</p> <p>18 seeing the patient for.</p> <p>19 Q. Sure. So are there different screening</p> <p>20 protocols for different risks -- different cancer risks?</p> <p>21 A. There are screening programs for -- there's</p> <p>22 individual decisions that are made based on a patient and</p> <p>23 the reason the patient's seeing me. For someone that has</p> <p>24 a high risk of developing malignancies, that could be one</p>	<p style="text-align: right;">Page 61</p> <p>1 Q. And also I think you said for heavy smokers?</p> <p>2 Did you say that? Do you design screening programs for</p> <p>3 patients of yours that are heavy smokers?</p> <p>4 A. I follow guidelines for patients that have --</p> <p>5 that are heavy smokers.</p> <p>6 Q. Which guidelines do you follow?</p> <p>7 A. The recommendation to do low-dose CAT scan</p> <p>8 annually which is an accepted screening protocol. It's</p> <p>9 in NCCN and I think other places as well.</p> <p>10 Q. Are there any other categories of patients,</p> <p>11 your patients that you screen regularly?</p> <p>12 A. I'm not sure I -- I understand the question,</p> <p>13 how to answer the question. Every patient I'm seeing is</p> <p>14 being screened regularly.</p> <p>15 Q. Okay. Well, you mentioned that you've</p> <p>16 designed screening programs for patients. Are there any</p> <p>17 other categories of patients other than what we've just</p> <p>18 spoken about that you have designed screening programs</p> <p>19 for in your practice?</p> <p>20 A. Patients that have family -- that have had</p> <p>21 family histories and -- of -- of -- of genetic</p> <p>22 abnormalities in high risk cancer that they themselves</p> <p>23 haven't had but because there's unknown mutations or</p> <p>24 there have been unknown mutations that may put those</p>

<p style="text-align: right;">Page 62</p> <p>1 patients at risk, I will create a more intense screening 2 program for that group of patients than for somebody that 3 didn't have any of that history. 4 Q. Any other categories? 5 A. Not that I can think of. 6 Q. Okay. Scroll down to or move down to the 7 next paragraph. You say you're compensated for this 8 matter at an hourly rate. What is your hourly rate? 9 A. My hourly rate for reviewing records is \$500 10 per hour. For deposition or courtroom testimony it's 11 \$600 per hour. 12 Q. So you're getting paid \$600 an hour to be 13 here today? 14 A. I believe so, yes. 15 Q. Are you confirming that? Is that what you're 16 doing now? 17 A. No. 18 Q. What are you looking at -- is that your 19 report? 20 A. That's the -- my -- my report. 21 Q. Okay. You also state in that paragraph that 22 the opinions you "state in this report are stated within 23 a reasonable degree of professional certainty." What 24 does that mean?</p>	<p style="text-align: right;">Page 64</p> <p>1 duration of use." What is that assumption based on? 2 A. Based on the information I was provided by 3 counsel. 4 Q. What information was that? 5 A. Information we've already discussed. It was 6 the reports of their experts. 7 Q. So that assumption in Section 2 is based on 8 the reports of their experts; correct? 9 A. Correct. 10 Q. Anything else? 11 A. No. 12 Q. Okay. And you also assume "that the medical 13 monitoring fund/program to be established can be 14 efficiently administered to ensure that people will only 15 receive funding for appropriate tests or intervention." 16 What is that based on? 17 A. So my charge was to create a medical 18 monitoring program for a class of patients. When I put 19 that together, I have no knowledge as to how -- how these 20 types of things are funded or -- or arranged 21 logistically. I just know that -- what medically makes 22 sense and that's what I put together in my report. 23 MR. KERNER: Could you read that answer back, 24 please.</p>
<p style="text-align: right;">Page 63</p> <p>1 MS. GEMAN: You can take the time you need to 2 look at the language. 3 BY THE WITNESS: 4 A. I think that's going to be true of any 5 opinions I have about anything. Nothing is set in stone. 6 It's going to be within what I consider -- what's 7 considered reasonable based on my profession. 8 BY MR. KERNER: 9 Q. Tell me what you mean by "professional 10 certainty." 11 A. In other words, based on my medical expertise 12 rather than just assumptions, lay assumptions. 13 Q. Is professional certainty different than 14 medical certainty? 15 A. Probably not. 16 Q. Did someone tell you to use that phrase? 17 A. No. 18 Q. Have you ever used it before? 19 A. I can't -- I can't recall. 20 Q. If you go to the top of the next page, you 21 say that in forming your opinions you've "assumed that 22 the people who took the Valsartan in question can be 23 identified along with identification of the manufacturers 24 of their pills, the dosage and levels of NDMA/NDEA and</p>	<p style="text-align: right;">Page 65</p> <p>1 (Requested portion of the 2 record read.) 3 BY MR. KERNER: 4 Q. And when you say "what medically makes 5 sense," is that based on your review of the reports from 6 Plaintiffs' experts? 7 A. No. What medically makes sense is based on 8 my -- my development of what I consider to be appropriate 9 screening for the patients that are at risk. 10 Q. And what you consider to be appropriate for 11 screening is based on what? 12 A. Is based on my understanding of the diseases 13 and my review of the literature as outlined. 14 Q. I'm sorry. I didn't hear it. 15 A. As outlined in my report. 16 Q. What about any of the guidelines that are -- 17 the NCCN guidelines, was that something you considered? 18 A. Yes. 19 Q. Does your screening program here vary from 20 the NCCN guidelines? 21 A. The NCCN guidelines don't specifically 22 outline the screening program especially for this 23 particular class of patients. It just outlines details 24 about risks and how they should be monitored.</p>

<p style="text-align: right;">Page 66</p> <p>1 Q. In paragraph 3, "Background," you say: "It's 2 been established that Valsartan API manufactured by 3 certain manufacturers here and sold to other companies 4 was contaminated with carcinogens, NDMA and NDEA." Do 5 you see that? 6 A. Yes. 7 Q. And who established that? 8 A. I don't know who established that. I know 9 that it's been established based on the -- on the reports 10 that I was given. 11 Q. Okay. Anything else -- based on anything 12 else or just the reports that you were given? 13 A. Just on the reports that I was given. 14 Q. Okay. Now, a little further down in 15 paragraph 3 you mention that you constructed a monitoring 16 protocol. The first thing you did was identify certain 17 cancers; correct? 18 A. Correct. 19 Q. And you did that based on the review of four 20 Plaintiffs' experts; correct? 21 A. Correct. 22 Q. So how did you do that? Explain how you did 23 that, please. 24 A. Explain how I did what?</p>	<p style="text-align: right;">Page 68</p> <p>1 BY THE WITNESS: 2 A. Yes. 3 BY MR. KERNER: 4 Q. What's your basis for that opinion? 5 A. My basis for the opinion is the evidence 6 provided that suggests that these cancers are at 7 increased risk of patients that have had exposure to that 8 carcinogen and the levels they had exposure to, so they 9 deserve to be monitored for those. 10 Q. And again that's based on the four 11 Plaintiffs' experts that you referred to? 12 A. Correct. 13 Q. Is there potential for some of the proposed 14 class members to be excluded from the screening for one 15 or more of the nine cancers that you outlined? 16 MS. GEMAN: Objection to the extent it calls 17 for a legal conclusion. 18 BY THE WITNESS: 19 A. Could you repeat the question? 20 BY MR. KERNER: 21 Q. Sure. Is there a potential for some of these 22 proposed class members to be excluded from screening, to 23 not be screened for one or more of the nine cancers you 24 outlined?</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. How you identified -- you said: "The 2 following cancers merit monitoring." You reviewed the 3 reports of these four experts, and what led you to 4 conclude that these nine cancers merited monitoring? 5 A. These nine cancers were identified as those 6 that were at higher risk based on the exposure to NDMA 7 and NDEA. 8 Q. By the experts that you relied on; correct? 9 A. Correct. 10 Q. Did you consider any other cancers? 11 A. No. 12 Q. So is it your opinion, Doctor, that every 13 proposed medical monitoring class member be screened for 14 each of these nine cancers? 15 A. The screening program that I outlined would 16 cover those nine cancers, nine classes of cancers. 17 Q. I understand that. We'll get to that 18 actually, but is it your testimony and is it your opinion 19 that all class members, proposed class members be 20 screened for all of the nine cancers? 21 A. Yes. 22 Q. Every single class member should be screened 23 for all nine cancers? 24 MS. GEMAN: Objection, asked and answered.</p>	<p style="text-align: right;">Page 69</p> <p>1 MS. GEMAN: Same objection. 2 BY THE WITNESS: 3 A. I don't understand -- I don't understand the 4 question. 5 BY MR. KERNER: 6 Q. Do you think there are any circumstances 7 where any of the potential class members wouldn't need to 8 be screened for all nine of these cancers? 9 MS. GEMAN: Objection. 10 BY THE WITNESS: 11 A. I think the basic screening is necessary for 12 every patient. I think individual patients would then 13 behoove us to look at different things based on that 14 patient, but the basic screening should be true for every 15 patient. 16 Q. Let's explore that. What would you look at 17 with respect to individual patients? 18 MS. GEMAN: Objection. 19 BY THE WITNESS: 20 A. You mean above and beyond the screening 21 program that's outlined? 22 MR. KERNER: Can you just read back his last 23 answer, please. 24</p>

<p style="text-align: right;">Page 70</p> <p>1 (Requested portion of the</p> <p>2 record read.)</p> <p>3 BY MR. KERNER:</p> <p>4 Q. Okay, Doctor. You said it would behoove us</p> <p>5 to look at different things for different patients. What</p> <p>6 things would you look at?</p> <p>7 A. Well, I think I mentioned in my report if</p> <p>8 somebody was a heavy smoker I may focus also on diseases</p> <p>9 associated with tobacco as I would do anyway even if they</p> <p>10 hadn't had this exposure, but this exposure may increase</p> <p>11 the risks that they have based on their own history, but</p> <p>12 yet everybody deserves at least the basic screening</p> <p>13 whatever their own history is. But any doctor's gonna</p> <p>14 look at a patient's individual problem. Someone has a</p> <p>15 pain in his arm, he's going to look at the arm.</p> <p>16 Q. Sure. And different patients might require</p> <p>17 different screening?</p> <p>18 MS. GEMAN: Objection.</p> <p>19 BY THE WITNESS:</p> <p>20 A. No. Different patients may require</p> <p>21 additional testing to the basic screening.</p> <p>22 BY MR. KERNER:</p> <p>23 Q. Is there any reason or could there be --</p> <p>24 Strike that.</p>	<p style="text-align: right;">Page 72</p> <p>1 recommend PSA?</p> <p>2 A. Yes.</p> <p>3 Q. What if they're 85 years old?</p> <p>4 A. Depends on the clinical status of the</p> <p>5 patient. If they're 85 and fit with a good performance</p> <p>6 status, yes.</p> <p>7 Q. Are there any male patients that you would</p> <p>8 not recommend a PSA for?</p> <p>9 A. Patient that declined to have it. Someone</p> <p>10 that's had a -- No, strike that. I -- I can't think of</p> <p>11 any other specific situations where I would not do PSA</p> <p>12 unless there -- as we mentioned someone, that was</p> <p>13 suffering from other medical conditions that would not</p> <p>14 allow for expectation of longevity.</p> <p>15 Q. What's the basis for performing a PSA on an</p> <p>16 80-year old man? What's the data or the support for</p> <p>17 that?</p> <p>18 A. Since there's no data on patients that are 80</p> <p>19 exposed to these carcinogens and since I have seen as</p> <p>20 others have elderly patients who have developed very</p> <p>21 aggressive prostate cancer and if caught early could</p> <p>22 be -- could be given the chance not to have to suffer</p> <p>23 from progressive metastatic disease, I would recommend</p> <p>24 doing PSA even in those patients because of the unique</p>
<p style="text-align: right;">Page 71</p> <p>1 Would there be any reason that you can think</p> <p>2 of based on medical history or comorbidities or anything</p> <p>3 like that for an individual patient where you wouldn't</p> <p>4 conduct the same screening for that patient? For</p> <p>5 example, would you recommend a colonoscopy every five</p> <p>6 years for someone who had a prior perforation?</p> <p>7 MS. GEMAN: Objection.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Well, as discussed before, a patient that's</p> <p>10 had a comorbidity or a problem related to a test would</p> <p>11 not be offered that test.</p> <p>12 BY MR. KERNER:</p> <p>13 Q. Sure. Okay. And say, for instance, giving</p> <p>14 another example, you list prostate cancer here in number</p> <p>15 6. What's the appropriate screening that you propose for</p> <p>16 prostate cancer?</p> <p>17 A. Well, first I would limit it to males.</p> <p>18 Q. Okay.</p> <p>19 A. The appropriate screening for prostate cancer</p> <p>20 would include a history to determine if there's any</p> <p>21 urinary symptoms, would include a physical examination</p> <p>22 which would include prostate exam as part of a regular</p> <p>23 physical and may include a blood test called a PSA.</p> <p>24 Q. And if the person is 80 years old, would you</p>	<p style="text-align: right;">Page 73</p> <p>1 situation where they've been exposed to these</p> <p>2 carcinogens.</p> <p>3 Q. So you'd recommend a PSA for a fit 90-year</p> <p>4 old man?</p> <p>5 A. Most likely, yes.</p> <p>6 Q. Okay. Are there any risks to the screening</p> <p>7 procedures that you're proposing?</p> <p>8 A. There are risks --</p> <p>9 MS. GEMAN: Objection.</p> <p>10 BY THE WITNESS:</p> <p>11 A. There are risks to everything. A blood draw,</p> <p>12 the needle could break off, you could get infection, you</p> <p>13 could have pain. Most of the things I'm recommending are</p> <p>14 within the limits of accepted risk for general</p> <p>15 population.</p> <p>16 BY MR. KERNER:</p> <p>17 Q. Are the risks the same for all individuals?</p> <p>18 A. No, of course not.</p> <p>19 Q. Why not?</p> <p>20 A. Because someone that's had a perforation from</p> <p>21 a colonoscopy may be at risk for that happening again.</p> <p>22 Someone that has other conditions of the colon which you</p> <p>23 didn't mention before like severe diverticulitis or</p> <p>24 diverticulosis may not be a good candidate for some of</p>

<p style="text-align: right;">Page 74</p> <p>1 the screening. So, of course, every person has to be 2 evaluated individually.</p> <p>3 Q. Okay. Are there cases where the risks will 4 outweigh the benefits?</p> <p>5 A. We've already alluded to some of those, yes.</p> <p>6 Q. And the answer's yes?</p> <p>7 A. Yes.</p> <p>8 Q. In paragraph 4 you talk about in conducting 9 the analysis you "assumed the Plaintiffs' experts are 10 correct that the levels, dosage and duration of use 11 were/are sufficient to increase one's risk of certain 12 cancers and to cause or contribute to causing cancers in 13 users," and you prepared this report consistent with 14 those assumptions. And you're relying on those 15 assumptions for your opinions in this report; correct?</p> <p>16 A. Correct.</p> <p>17 Q. In the next paragraph you say: "In order to 18 qualify for medical monitoring, class members must have 19 ingested a cumulative amount of NDMA from both the 20 Valsartan pills and their diet and they've reached the 21 lifetime cumulative exposures associated with 22 statistically significant increased risks in dietary and 23 other studies." Did I read that correctly?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 76</p> <p>1 toxins, that they are in a class that may be at risk for 2 developing certain things.</p> <p>3 Q. You say that's your assumption. What is that 4 assumption based on?</p> <p>5 A. That's my understanding.</p> <p>6 Q. What is that understanding based on?</p> <p>7 A. What -- my knowledge of the English language.</p> <p>8 Q. Okay. So is lifetime cumulative threshold a 9 term that you've used in your medical practice over the 10 years?</p> <p>11 A. No. It's a term I've seen in the reports.</p> <p>12 Q. And that's the first time you've seen it was 13 in this report?</p> <p>14 A. Probably.</p> <p>15 Q. Now you talk about the cumulative amount of 16 NDMA from both the Valsartan pills and their diet reached 17 a lifetime cumulative exposure. You see that in that 18 paragraph; right?</p> <p>19 A. Can you repeat that, please.</p> <p>20 Q. Sure. I'm sorry. In that same paragraph, 21 you talk about that "the class member must have ingested 22 a cumulative amount of NDMA from both the Valsartan pills 23 and their diet that they've reached lifetime cumulative 24 exposures." Do you see that?</p>
<p style="text-align: right;">Page 75</p> <p>1 Q. What is lifetime cumulative exposure?</p> <p>2 A. The amount of exposure they've had to NDMA 3 and NDEA.</p> <p>4 Q. Is that a term that you've used in your 5 medical practice over the years?</p> <p>6 A. What's that?</p> <p>7 Q. Lifetime cumulative exposure.</p> <p>8 A. I've used that in regards to many things -- 9 exposure to tobacco, exposure to certain chemotherapeutic 10 drugs where the cumulative toxicity has to do with 11 lifetime exposure, a drug called Adriamycin. Your whole 12 life you're at certain risk if you've had cumulative 13 exposure, so yes, I use that term all the time.</p> <p>14 Q. Are you familiar with the term lifetime 15 cumulative threshold?</p> <p>16 A. I'm -- I know what that means but what do you 17 mean am I --</p> <p>18 Q. So you know what it means. What does it mean 19 to you?</p> <p>20 A. Could you repeat the question?</p> <p>21 Q. Lifetime cumulative threshold.</p> <p>22 A. My assumption is that that means that when 23 someone's reached a certain level of exposure like with 24 radiation exposure, like with the drugs, like with these</p>	<p style="text-align: right;">Page 77</p> <p>1 A. I do.</p> <p>2 Q. Is NDMA something that you can be exposed to 3 from your diet?</p> <p>4 A. I believe that the nitrosamine -- the 5 nitrosamines you're exposed to in -- in certain food 6 types.</p> <p>7 Q. What food types?</p> <p>8 A. Prepared foods, coldcuts, bacon, things where 9 nitrates are used as preservative or naturally occurring.</p> <p>10 Q. What about fresh fruit?</p> <p>11 A. I'm not -- I'm not certain.</p> <p>12 Q. Vegetables?</p> <p>13 A. I don't know.</p> <p>14 Q. How can you tell the level of NDMA -- Strike 15 that.</p> <p>16 How can you tell whether the level of NDMA is 17 from the Valsartan pill or your diet?</p> <p>18 A. I don't -- I don't know that you can tell.</p> <p>19 Q. And are you familiar with indigenous NDMA?</p> <p>20 A. Yes.</p> <p>21 Q. What is that?</p> <p>22 A. NDMA that's just present in the body.</p> <p>23 Q. You don't mention that in your report?</p> <p>24 A. No.</p>

<p style="text-align: right;">Page 78</p> <p>1 Q. Is indigenous NDMA, can that be part of a</p> <p>2 lifetime cumulative exposure?</p> <p>3 A. Yes.</p> <p>4 Q. So it's the Valsartan pill, it's your diet</p> <p>5 and it's the indigenous NDMA; correct --</p> <p>6 A. Correct.</p> <p>7 MS. GEMAN: Objection, vague.</p> <p>8 BY MR. KERNER:</p> <p>9 Q. -- that are all -- that all can be part of</p> <p>10 lifetime cumulative exposure as you used that term here</p> <p>11 in your report; correct?</p> <p>12 A. Correct.</p> <p>13 Q. And am I correct that there's no way to</p> <p>14 identify what percentage of NDMA comes from which</p> <p>15 factor -- the Valsartan pill, the diet or the indigenous</p> <p>16 NDMA?</p> <p>17 A. I think and my understanding of the experts'</p> <p>18 evaluation is that the amount of NDMA found in the vast</p> <p>19 majority of people from indigenous or naturally occurring</p> <p>20 substances is quite lower than from a toxic -- the toxic</p> <p>21 levels that were found in the product that we're</p> <p>22 discussing, so --</p> <p>23 Q. What -- sorry.</p> <p>24 A. -- it's unlikely that somebody would have</p>	<p style="text-align: right;">Page 80</p> <p>1 reasonable degree of medical certainty that there exists</p> <p>2 diagnostic tests that can mitigate the risks of</p> <p>3 developing cancer faced by the class of people because of</p> <p>4 their exposure to contaminated Valsartan who have a level</p> <p>5 of exposure equal to the LTC and this program --" meaning</p> <p>6 your program; correct?</p> <p>7 A. Yes.</p> <p>8 Q. "-- is different than the one that would have</p> <p>9 been prescribed in the absence of that particular</p> <p>10 exposure and increased risk." Did I read that correctly?</p> <p>11 A. Yes.</p> <p>12 Q. So a few things I want to talk to you about</p> <p>13 in that sentence. You hold an opinion to a reasonable</p> <p>14 degree of medical certainty that there are diagnostic</p> <p>15 tests that mitigate the risk of developing cancer;</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. Now, you don't mean that there are tests that</p> <p>19 can prevent you from developing cancer, do you?</p> <p>20 A. There are.</p> <p>21 Q. What are they?</p> <p>22 A. Colonoscopy, for example.</p> <p>23 Q. Any others?</p> <p>24 A. Repeat -- can you repeat the question?</p>
<p style="text-align: right;">Page 79</p> <p>1 just from those other things enough exposure, enough</p> <p>2 levels to render them at significant risk. While there's</p> <p>3 so much more exposure from the tainted Valsartan, that</p> <p>4 it's -- it makes it a much more important issue.</p> <p>5 Q. What's your basis for that statement?</p> <p>6 A. The experts' review of this.</p> <p>7 Q. So other than the Plaintiffs' other experts</p> <p>8 you have no idea what percentage of NDMA comes from</p> <p>9 Valsartan, diet or indigenous production; correct?</p> <p>10 A. Correct.</p> <p>11 Q. And, by the way, with respect to lifetime</p> <p>12 cumulative exposure, you have not independently evaluated</p> <p>13 or determined the lifetime cumulative exposure for NDMA</p> <p>14 or NDEA; correct?</p> <p>15 A. That was not my -- my role in that. I have</p> <p>16 not done that.</p> <p>17 Q. So I'm correct?</p> <p>18 A. Yes.</p> <p>19 Q. Prior to this litigation -- Strike that.</p> <p>20 Let's go to the bottom of Page 3, please,</p> <p>21 your "Opinion on Medical Monitoring." Do you see that</p> <p>22 paragraph?</p> <p>23 A. Yes.</p> <p>24 Q. You say that it's your "opinion to a</p>	<p style="text-align: right;">Page 81</p> <p>1 MR. KERNER: Can you read it back, please.</p> <p>2 (Requested portion of the</p> <p>3 record read.)</p> <p>4 BY THE WITNESS:</p> <p>5 A. Yes. Upper endoscopy, detection of Barrett's</p> <p>6 esophagus, Pap smear, detection of pre-malignant changes.</p> <p>7 Mammogram even can detect ductal carcinoma insitu or</p> <p>8 other conditions that are considered pre-malignant.</p> <p>9 Evaluation of the liver to look for cirrhosis can</p> <p>10 predispose to the -- or fatty liver can be a precursor to</p> <p>11 developing -- to developing hepatocellular cancer.</p> <p>12 Evaluation of the pancreas can find -- can find certain</p> <p>13 ductal cystic changes that may be precursors to cancer.</p> <p>14 That's off the top of my head things that I can think of</p> <p>15 where it would predict or even prevent cancer.</p> <p>16 BY MR. KERNER:</p> <p>17 Q. And you talk about class of people because of</p> <p>18 their exposure to contaminated Valsartan?</p> <p>19 A. Correct.</p> <p>20 Q. And to that you're talking about people who</p> <p>21 have an exposure greater than or equal to the LCT which</p> <p>22 is a term you learned in your report for the first time?</p> <p>23 A. Correct.</p> <p>24 MS. GEMAN: Objection, misstates the</p>

<p style="text-align: right;">Page 82</p> <p>1 testimony.</p> <p>2 BY MR. KERNER:</p> <p>3 Q. You say: "This program is different than the</p> <p>4 one that would have been prescribed in the absence of</p> <p>5 that particular exposure." Can you -- can you tell me</p> <p>6 what that sentence means?</p> <p>7 A. The whole point of a medical monitoring</p> <p>8 program for people that have been exposed is that we're</p> <p>9 doing more than I would do with a normal, healthy person</p> <p>10 that just came in the office.</p> <p>11 Q. Okay. But what this says is that "The</p> <p>12 program is different than one that would have been</p> <p>13 prescribed in the absence of that particular exposure."</p> <p>14 I think you mean Valsartan; correct --</p> <p>15 A. Correct.</p> <p>16 Q. -- and increased risk?</p> <p>17 And you link that to the exposure being</p> <p>18 greater than or equal to the LCT; correct?</p> <p>19 A. Correct.</p> <p>20 Q. Do you know if it's possible to reach the LCT</p> <p>21 based on endogenous NDMA and diet without Valsartan?</p> <p>22 A. I do not know the answer to that, but as I</p> <p>23 stated in my report, I could modify my opinion. At this</p> <p>24 point I would think that if somebody does show that</p>	<p style="text-align: right;">Page 84</p> <p>1 testimony.</p> <p>2 MR. KERNER: Can you read back my question,</p> <p>3 please.</p> <p>4 (Requested portion of the</p> <p>5 record read.)</p> <p>6 MS. GEMAN: Vague as to --</p> <p>7 MR. KERNER: I will rephrase that.</p> <p>8 MS. GEMAN: Yeah.</p> <p>9 BY MR. KERNER:</p> <p>10 Q. If a patient reached the LCT without any</p> <p>11 Valsartan exposure, would you recommend the same program?</p> <p>12 MS. GEMAN: Objection, vague, incomplete</p> <p>13 hypothetical.</p> <p>14 BY THE WITNESS:</p> <p>15 A. I was not asked to consider that, but I think</p> <p>16 it's worth evaluating.</p> <p>17 BY MR. KERNER:</p> <p>18 Q. And you just said you're modifying your</p> <p>19 opinion. What were you modifying your opinion to?</p> <p>20 MS. GEMAN: Objection, misstates testimony.</p> <p>21 BY THE WITNESS:</p> <p>22 A. I didn't say I was modifying my opinion. I</p> <p>23 was saying I would -- I would likely include anybody that</p> <p>24 could be shown to -- as I said, someone that reached</p>
<p style="text-align: right;">Page 83</p> <p>1 they've reached the LCT wherever their exposure to the</p> <p>2 nitrosamines is that they would be appropriate for the</p> <p>3 screening tests that I --</p> <p>4 Q. Even without Valsartan?</p> <p>5 A. Yes. Yes.</p> <p>6 Q. And so you would -- you would agree with me</p> <p>7 then that it's possible to -- Strike that.</p> <p>8 You don't know whether it's possible to reach</p> <p>9 the lifetime cumulative threshold without Valsartan;</p> <p>10 correct?</p> <p>11 A. Correct.</p> <p>12 Q. And you have no idea; correct?</p> <p>13 A. From what I've read, it sounds like it's not</p> <p>14 likely to reach the levels that were reached with the</p> <p>15 Valsartan exposure.</p> <p>16 Q. And to be clear, when you say "from what I've</p> <p>17 read," it's from relying on Plaintiffs' other experts --</p> <p>18 A. Correct.</p> <p>19 Q. -- correct?</p> <p>20 But your opinion now it sounds like has been</p> <p>21 modified to now say that if you've reached the LCT</p> <p>22 without any Valsartan exposure, you would propose the</p> <p>23 same program; correct?</p> <p>24 MS. GEMAN: No. Objection, misstates the</p>	<p style="text-align: right;">Page 85</p> <p>1 those levels should have this monitoring, so if that</p> <p>2 level came from somewhere else, I don't see why I</p> <p>3 wouldn't include them in that.</p> <p>4 BY MR. KERNER:</p> <p>5 Q. And do you do that with your patients now?</p> <p>6 A. Do I do what?</p> <p>7 Q. Do you screen your patients with this kind of</p> <p>8 exposure now? Do you screen your patients the way you're</p> <p>9 describing it for anybody who has achieved this LCT?</p> <p>10 MS. GEMAN: Objection, vague.</p> <p>11 BY THE WITNESS:</p> <p>12 A. No, I have no way of monitoring that. I have</p> <p>13 no way of evaluating for that.</p> <p>14 BY MR. KERNER:</p> <p>15 Q. You have no way of evaluating what -- whether</p> <p>16 they reached the LCT?</p> <p>17 A. Routinely -- routinely testing for levels of</p> <p>18 nitrosamines in a person's body.</p> <p>19 Q. You're not aware of any test that can</p> <p>20 determine the lifetime cumulative threshold, are you?</p> <p>21 A. I'm not aware of clinically available tests</p> <p>22 to monitor for that.</p> <p>23 Q. And, again, to be specific, lifetime</p> <p>24 cumulative threshold of nitrosamine or NDMA --</p>

<p style="text-align: right;">Page 86</p> <p>1 A. Correct.</p> <p>2 Q. -- or NDEA; correct?</p> <p>3 MS. GEMAN: I was going to jump in to say can</p> <p>4 I have that question read. You were speaking very</p> <p>5 quickly. I'm sorry.</p> <p>6 (Requested portion of the</p> <p>7 record read.)</p> <p>8 MS. GEMAN: Objection.</p> <p>9 MR. KERNER: Read that back again, please.</p> <p>10 (Requested portion of the</p> <p>11 record read.)</p> <p>12 BY MR. KERNER:</p> <p>13 Q. Let's move on to Page 4. You talk about</p> <p>14 specialized testing in Section 2 there. Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. You talk about -- is it Galleri or Galleri?</p> <p>17 A. Galleri.</p> <p>18 Q. And you say that "early detection or similar</p> <p>19 liquid biopsy should be performed annually." On Page 5</p> <p>20 you again mention Galleri, and you say that "it has been</p> <p>21 shown to detect certain cancers such as pancreatic and</p> <p>22 esophageal cancer." Where is the -- what is the data to</p> <p>23 support annual Galleri testing?</p> <p>24 MS. GEMAN: Objection.</p>	<p style="text-align: right;">Page 88</p> <p>1 in August to allow Medicare to -- to insist that Medicare</p> <p>2 cover this testing because of its -- its ability to</p> <p>3 detect cancers earlier.</p> <p>4 MR. KERNER: Great. I move to strike that as</p> <p>5 nonresponsive.</p> <p>6 BY MR. KERNER:</p> <p>7 Q. My question is do you know of any guidelines</p> <p>8 or any organization that supports annual testing of</p> <p>9 Galleri.</p> <p>10 A. No.</p> <p>11 MS. GEMAN: Objection, asked and answered.</p> <p>12 MR. KERNER: Now it's been answered.</p> <p>13 BY MR. KERNER:</p> <p>14 Q. You mentioned that Galleri has been shown to</p> <p>15 detect certain cancers such as pancreatic and esophageal</p> <p>16 cancer; correct?</p> <p>17 A. Correct.</p> <p>18 Q. That's what it says.</p> <p>19 Okay. You also recommend Cologuard for colon</p> <p>20 cancer?</p> <p>21 A. Correct.</p> <p>22 Q. And you recommend colonoscopy every five</p> <p>23 years and an upper endoscopy every five years; correct?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 87</p> <p>1 BY THE WITNESS:</p> <p>2 A. The recommendation to do annual testing is</p> <p>3 based on my own program recommending screening, and I'm</p> <p>4 recommending the patient be seen by a physician at least</p> <p>5 annually, so I would include that as part of the routine</p> <p>6 blood tests and evaluations.</p> <p>7 Q. Right. And my question is a little</p> <p>8 different. Other than your own recommendation, and I</p> <p>9 appreciate that, what is the data that supports Galleri,</p> <p>10 Galleri's annual testing?</p> <p>11 MS. GEMAN: Vague.</p> <p>12 BY THE WITNESS:</p> <p>13 A. There's data that shows Galleri can detect</p> <p>14 cancers in earlier stages.</p> <p>15 BY MR. KERNER:</p> <p>16 Q. And is that part of any guidelines from NCCN</p> <p>17 or any other organization?</p> <p>18 A. No.</p> <p>19 Q. Do you know of any organization that</p> <p>20 recommends annual testing with Galleri?</p> <p>21 A. I know that the American Cancer Society</p> <p>22 has -- has suggested utilizing this test for evaluating</p> <p>23 patients, and they're involved in -- in co -- in</p> <p>24 sponsoring of a bill that -- that was brought to Congress</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. So for every patient who has -- every patient</p> <p>2 on the planet who has achieved this LCT that you've</p> <p>3 learned of in this litigation for the first time, you</p> <p>4 want them to have a colonoscopy and an upper GI endoscopy</p> <p>5 every five years?</p> <p>6 MS. GEMAN: Objection, misstates the opinion,</p> <p>7 misstates testimony, misstates the report, calls for a</p> <p>8 legal conclusion by the class definition.</p> <p>9 BY MR. KERNER:</p> <p>10 Q. Is that correct?</p> <p>11 A. I don't understand.</p> <p>12 Q. Any class member, any proposed class member</p> <p>13 you're suggesting -- Strike that.</p> <p>14 You're recommending that every single</p> <p>15 proposed class member has a colonoscopy and an upper</p> <p>16 endoscopy every five years regardless of comorbidities,</p> <p>17 regardless of other past history; correct?</p> <p>18 A. My recommendations are guidelines that are</p> <p>19 recommendations for patients and their doctors to</p> <p>20 consider using, so that would be taken into account when</p> <p>21 deciding on that test.</p> <p>22 Q. So -- okay. I appreciate that. And so am I</p> <p>23 correct that you think ultimately the decision is to be</p> <p>24 made by the individual and his or her treating physician</p>

<p style="text-align: right;">Page 90</p> <p>1 as to what particular procedure is appropriate for them, 2 for that person?</p> <p>3 A. I'm -- I'm outlining a guideline because of 4 the exposure that can help guide the patient and the 5 doctor in determining -- in determining whether to follow 6 exactly the guideline or make individual recommendations, 7 yes.</p> <p>8 Q. And I didn't include the low-dose CT chest 9 scan annually. It's your recommendation that any 10 proposed class member has a CT scan once a year?</p> <p>11 A. No, I don't believe I said that. 12 (Witness peruses document.)</p> <p>13 Q. Page 4.</p> <p>14 A. Okay.</p> <p>15 Q. You do say that; correct?</p> <p>16 A. Yes. I'm sorry. Because of the exposure 17 that put them at the same risk as someone who'd been a 18 smoker.</p> <p>19 Q. And your opinion -- that's your opinion, that 20 the exposure to NDMA or nitrosamines puts them at the 21 same risk as a smoker?</p> <p>22 A. Based on the estimate of exposure and risk of 23 lung cancer from that exposure, yes.</p> <p>24 Q. On whose estimate? Based on whose estimate?</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. Okay. I don't see any other screening 2 identified in your report. Do you -- do you think that 3 those are the -- are those the cancers that you would 4 screen for -- pancreatic, esophageal, colorectal and lung 5 cancer?</p> <p>6 MS. GEMAN: Objection, misstates testimony, 7 asked and answered.</p> <p>8 BY THE WITNESS:</p> <p>9 A. There's two things there. There's -- the 10 first is that the Galleri, what you're reading is using 11 pancreatic and esophageal as examples. It's not listing 12 all the cancers it's screening for, and the reason it was 13 listed as examples is because there's not good 14 screening -- screening tests for detecting those early. 15 The Galleri could, but the Galleri's good for almost 16 every cancer. That's the point of the Galleri. The -- 17 the other thing is that's not the only testing. If you 18 look in my program, it includes the annual laboratory 19 studies, exam, history, and those that you're referring 20 to are just specialized testing in addition that I felt 21 was -- was appropriate in order to help detect cancer in 22 earlier stages.</p> <p>23 BY MR. KERNER:</p> <p>24 Q. Where in your report do you talk about</p>
<p style="text-align: right;">Page 91</p> <p>1 A. The Plaintiff experts that estimated the 2 relative risk of 1.05 to 3.3 for lung cancer.</p> <p>3 Q. So, again, this is basically just based on 4 what the Plaintiffs' experts have opined; correct?</p> <p>5 A. Correct.</p> <p>6 Q. So, Doctor, what I see in your report is you 7 seem to be recommending in some form or another the 8 Galleri which you say can detect certain cancers such as 9 pancreatic and esophageal; correct?</p> <p>10 A. Can you tell me where you're looking, please.</p> <p>11 Q. Yeah. That's on Page 5. Under "Colonoscopy 12 and Fecal DNA testing" you mention that -- I'm sorry. 13 Under "Galleri" you mention that Galleri is known to 14 detect certain cancers such as pancreatic and esophageal. 15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And you also have a section on 18 colonoscopy for detecting colon or rectal cancer; 19 correct?</p> <p>20 A. Correct.</p> <p>21 Q. And then you also discuss a little further up 22 I believe, and we just talked about it briefly, the CT 23 chest scan. Is that for lung cancer?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 93</p> <p>1 screening for bladder cancer?</p> <p>2 A. So I don't talk specifically about bladder 3 cancer. It's listed with the other cancers in here, and 4 that would be included in the history because there'll be 5 unique things to -- to patients that have bladder cancer. 6 In the physical examination, laboratory tests could 7 determine -- could be a way to screen for bladder along 8 with others and then the Galleri which can also detect 9 urinary tract cancers and other cancers in earlier 10 stages.</p> <p>11 Q. And what about liver cancer?</p> <p>12 A. And liver cancer as well.</p> <p>13 Q. Galleri?</p> <p>14 A. Galleri, but also the things we mentioned. 15 Liver cancer would have signs usually of cirrhosis or 16 hepatic steatosis, fatty liver, and that can be detected 17 by examinations and by laboratory tests and by history.</p> <p>18 Q. And if you can help me out here. Which 19 laboratory tests in your report are you referring to with 20 respect to liver cancer?</p> <p>21 A. Liver enzymes.</p> <p>22 Q. Where is that?</p> <p>23 A. 1C: "Laboratory tests to include blood 24 smear, basic chemistry profile which includes liver</p>

<p style="text-align: right;">Page 94</p> <p>1 enzymes, kidney function and other labs."</p> <p>2 Q. Okay. Doctor, in paragraph 6 or Section 6,</p> <p>3 you say midway through the paragraph that you "certify</p> <p>4 that the monitoring proposals detailed above have the</p> <p>5 potential to significantly improve the outcomes of</p> <p>6 patients that may be destined to develop malignancies due</p> <p>7 to their exposures and do not pose any significant risks</p> <p>8 or negative consequences." Do you see that?</p> <p>9 MS. GEMAN: Just object to the extent --</p> <p>10 MR. KERNER: Excuse me?</p> <p>11 MS. GEMAN: I just note that the report speaks</p> <p>12 for itself.</p> <p>13 MR. KERNER: Sure.</p> <p>14 MS. GEMAN: You're paraphrasing.</p> <p>15 BY MR. KERNER:</p> <p>16 Q. Well, what I read, did I read that correctly?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. What do you mean by "I certify that</p> <p>19 the monitoring proposals have the potential to</p> <p>20 significantly improve the outcomes?" Are you</p> <p>21 guaranteeing it?</p> <p>22 MS. GEMAN: Objection.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Is your question what do I mean by "certify"?</p>	<p style="text-align: right;">Page 96</p> <p>1 MS. GEMAN: Objection, vague.</p> <p>2 BY THE WITNESS:</p> <p>3 A. As I stated before, anything you do including</p> <p>4 a needle stick or walking in a room -- I didn't state</p> <p>5 that before; I'm stating it now -- has risks.</p> <p>6 Q. And that's all I'm asking, right.</p> <p>7 MS. GEMAN: Objection, calls for speculation.</p> <p>8 BY MR. KERNER:</p> <p>9 Q. Doctor, in your practice, have you ever</p> <p>10 concluded that any patient's cancer was caused by NDMA or</p> <p>11 NDEA?</p> <p>12 A. I've never had the opportunity to do that,</p> <p>13 no.</p> <p>14 Q. So the answer's no, you have not?</p> <p>15 MS. GEMAN: Objection, asked and answered.</p> <p>16 BY THE WITNESS:</p> <p>17 A. No.</p> <p>18 BY MR. KERNER:</p> <p>19 Q. Over the course of your career how many</p> <p>20 patients have you treated ballpark?</p> <p>21 A. 20,000 to 30,000.</p> <p>22 Q. Out of that universe of patients, how many of</p> <p>23 them were cancer patients?</p> <p>24 A. Eighty percent.</p>
<p style="text-align: right;">Page 95</p> <p>1 BY MR. KERNER:</p> <p>2 Q. Yes, sir.</p> <p>3 A. It means that to the best of my medical</p> <p>4 knowledge and ability I believe that this does what it's</p> <p>5 stated to do.</p> <p>6 Q. It's your opinion?</p> <p>7 A. Correct.</p> <p>8 Q. Did somebody tell you to use the word</p> <p>9 "certify" in there?</p> <p>10 A. No.</p> <p>11 Q. You also say that: "These exposures do not</p> <p>12 pose any --" I'm sorry. "This monitoring proposal do not</p> <p>13 pose any significant risks or negative consequences."</p> <p>14 MS. GEMAN: Objection. Again, it misstates</p> <p>15 the report. It says: "As detailed in Dr. Catenacci's</p> <p>16 report."</p> <p>17 MR. KERNER: Yes.</p> <p>18 BY THE WITNESS:</p> <p>19 A. There's a report that's been stricken, and</p> <p>20 the details of that report is what I was addressing.</p> <p>21 BY MR. KERNER:</p> <p>22 Q. But we would agree, I think you've already</p> <p>23 agreed, that there could be risks or negative</p> <p>24 consequences to certain procedures; correct?</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. Okay. Out of that number, how many of those</p> <p>2 patients did you make a determination as to the actual</p> <p>3 cause of their cancer?</p> <p>4 A. I'm actually not in the habit of making</p> <p>5 determination as to cause of cancers usually.</p> <p>6 Q. And you're not opining here about causation</p> <p>7 of any of the proposed class members; correct?</p> <p>8 A. Correct.</p> <p>9 Q. In your report on Page 4, in C you talk about</p> <p>10 "Periodic testing." Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. And for the colonoscopy you do say every five</p> <p>13 years as for screening in moderately high risk patients?</p> <p>14 A. Correct.</p> <p>15 Q. What makes a patient moderately high risk?</p> <p>16 A. I believe that's outlined in the NCCN</p> <p>17 guidelines, but moderately high risk patients would be</p> <p>18 somebody that had had a polyp, a pre-malignant polyp, an</p> <p>19 adenomatous polyp. I think that would be the main</p> <p>20 definition.</p> <p>21 Q. With the proposed class members, have you</p> <p>22 considered in your program the likelihood of reduced</p> <p>23 mortality?</p> <p>24 A. Could you --</p>

<p style="text-align: right;">Page 98</p> <p>1 Q. Are you considering whether the screening is 2 appropriate? 3 A. Could you repeat the question? 4 MR. KERNER: Can you read it back, please. 5 (Requested portion of the 6 record read.) 7 BY THE WITNESS: 8 A. I believe by definition of what we're doing 9 the point is to reduce mortality and morbidity. 10 BY MR. KERNER: 11 Q. And do we have -- do you have, Doctor, any 12 specific data for each of the tests that you're proposing 13 on whether it, in fact, does that? 14 A. Not specifically, no. 15 Q. This is just your -- Well, strike that. 16 Okay. 17 A. Could we go back to that last question? 18 Q. Sure. 19 THE WITNESS: Can you read that back? 20 (Requested portion of the 21 record read.) 22 BY THE WITNESS: 23 A. I mean there is data, for example, with 24 low-dose CAT scans for lung cancer that it does reduce</p>	<p style="text-align: right;">Page 100</p> <p>1 BY MR. KERNER: 2 Q. Sure. You can't point to any medical 3 literature or authoritative source that has actually 4 determined that exposure to NDMA or NDEA reasonably 5 necessitates the kind of medical monitoring for cancer in 6 humans, can you? 7 MS. GEMAN: Objection. 8 BY THE WITNESS: 9 A. I haven't investigated that. I know 10 literature exists because the reports that have come out 11 were based on it. Plus I know the FDA withdrew the drug 12 in a -- in a rapid manner because of their determination 13 there was some risk. That's all I know. 14 BY MR. KERNER: 15 Q. Okay. So but my question is are you aware of 16 any medical literature or authoritative source that 17 determined the kind of medical monitoring that you're 18 proposing for cancer in humans is appropriate for -- 19 because of exposure to NDMA or NDEA. 20 MS. GEMAN: Objection, asked and answered, 21 vague. 22 BY THE WITNESS: 23 A. There's medical literature to support the 24 monitoring for patients at risk, at similar risk to what</p>
<p style="text-align: right;">Page 99</p> <p>1 morbidity and mortality by detecting cancer earlier, so 2 there is data. You asked if I specifically had data for 3 this, so that's the answer. 4 MR. KERNER: Okay. I actually need to take a 5 two-minute comfort break, and we'll come right back. 6 THE VIDEOGRAPHER: The time now is 11:34 a.m. 7 This is the end of media four. We're off the record. 8 (WHEREUPON, a break was 9 taken.) 10 The time is now 11:56 a.m. This is the 11 beginning of media five. We're back on the record. 12 BY MR. KERNER: 13 Q. Dr. Kaplan, we're not quite there yet, so 14 we're going to just keep chugging along. All right? 15 A. Yes, sir. 16 Q. All right. A few questions here. 17 You can't point to any medical literature or 18 authoritative source that has actually determined that 19 exposure to NDMA or NDEA reasonably necessitates any sort 20 of medical monitoring for cancer in humans, can you? 21 MS. GEMAN: Objection. 22 BY THE WITNESS: 23 A. Can you repeat that, please. 24</p>	<p style="text-align: right;">Page 101</p> <p>1 we've determined or what has been determined for the risk 2 for the specific agents but no, not literature 3 specifically that I know of addressing that and the 4 monitoring. 5 BY MR. KERNER: 6 Q. And by "that" you mean NDMA and NDEA? 7 A. NDMA and NDEA, correct. 8 Q. So the answer to my question is no, you're 9 not aware of any medical literature or authoritative 10 source that determined medical monitoring for NDMA -- as 11 a result of NDMA and NDEA exposure is appropriate -- 12 MS. GEMAN: Objection. 13 BY MR. KERNER: 14 Q. -- correct? 15 A. I've never seen literature that -- yes. 16 MR. KERNER: Did you get that? 17 THE REPORTER: Yes. 18 MR. KERNER: I just saw you tilt your head. 19 BY MR. KERNER: 20 Q. Doctor, you're not offering any specific 21 criticisms or opinions about what a specific Defendant 22 did or didn't do with respect to Valsartan, are you? 23 A. I'm not opining to that, no. 24 Q. And you're not offering any opinion that NDMA</p>

Page 102	Page 104
<p>1 or NDEA causes cancer, are you?</p> <p>2 A. I'm not being asked to opine to that.</p> <p>3 Q. So you're not?</p> <p>4 A. I'm using that assumption.</p> <p>5 Q. But you -- you're not offering the opinion</p> <p>6 that NDMA or NDEA causes cancer; correct?</p> <p>7 A. I'm suggesting that that's a truism which is</p> <p>8 why I've created this monitoring, so I guess I'm offering</p> <p>9 that opinion based on -- I'm offering that as a statement</p> <p>10 of fact.</p> <p>11 Q. Based on what?</p> <p>12 A. Based on the reports I've read.</p> <p>13 Q. You haven't independently assessed the</p> <p>14 carcinogenicity of NDMA or NDEA; correct?</p> <p>15 A. Correct, I have not independently assessed</p> <p>16 any of that.</p> <p>17 Q. And you're not offering any opinion that</p> <p>18 Defendants' Valsartan products cause cancer; correct?</p> <p>19 A. Could you repeat that, please.</p> <p>20 Q. Sure. I'm going to do it this way. You</p> <p>21 haven't independently assessed the -- whether or not the</p> <p>22 Defendants' Valsartan products cause cancer?</p> <p>23 A. I have not independently assessed that.</p> <p>24 Q. So you won't be opining on that; correct?</p>	<p>1 you it is, and I know we discussed this off the record.</p> <p>2 I don't want to take a lot of time.</p> <p>3 And, Doctor, I just want to make sure.</p> <p>4 You've told me all of your opinions that you hold with</p> <p>5 respect to the case now; correct?</p> <p>6 A. I've -- all that I've been asked about, yes.</p> <p>7 Q. Well, are there other opinions that you hold</p> <p>8 that you are going to testify to?</p> <p>9 A. Not that I know of.</p> <p>10 Q. Okay. And so we've discussed the facts that</p> <p>11 support those opinions; correct?</p> <p>12 A. Correct.</p> <p>13 Q. And you feel like you've had a chance to</p> <p>14 state your opinions during this deposition?</p> <p>15 MS. GEMAN: Objection.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Yes.</p> <p>18 MR. KERNER: Okay. I'm going to pass the</p> <p>19 witness now.</p> <p>20 MS. ISIDRO: Are there others on the Zoom who</p> <p>21 would like to ask any questions?</p> <p>22 MS. LOTMAN: Yes. This is Alyson Lotman. I'm</p> <p>23 going to have a few. Give me one minute.</p> <p>24 MS. GEMAN: Alyson, can you state your</p>
Page 103	Page 105
<p>1 A. I won't be opining on -- I won't -- I</p> <p>2 really --</p> <p>3 MS. GEMAN: Do you understand the question?</p> <p>4 MR. KERNER: Yeah.</p> <p>5 MS. GEMAN: Answer it.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Well, not exactly. I'm not specifically</p> <p>8 looking at the data to opine that the drugs with the</p> <p>9 contaminants have led to cancer, but I'm using others who</p> <p>10 have done that in order to -- to justify and create my</p> <p>11 program.</p> <p>12 BY MR. KERNER:</p> <p>13 Q. I understand that. And the others, again, I</p> <p>14 want to be specific, are the Plaintiffs' experts --</p> <p>15 A. Correct.</p> <p>16 Q. -- correct?</p> <p>17 Doctor, I'm going to move -- I'm going to end</p> <p>18 my testimony -- end my questioning for the time being,</p> <p>19 but a couple of ministerial things first.</p> <p>20 Rachel, as we talked about, we've got -- I</p> <p>21 want to mark as Exhibit 4 the thumb drive that we</p> <p>22 discussed which contains the files that you produced on</p> <p>23 Monday. So we'll mark that as Exhibit 4. You can review</p> <p>24 it. You can look at it to make sure it is what we tell</p>	<p>1 appearance and which Defendant you represent and firm?</p> <p>2 This is Rachel Geman speaking. Thank you.</p> <p>3 MS. LOTMAN: Alyson Lotman from Duane Morris.</p> <p>4 I represent the HP Defendants.</p> <p>5 I apologize. If someone else has a few,</p> <p>6 wants to go before me. I'm just trying to close some</p> <p>7 screens before I can get on.</p> <p>8 Are we still on the record?</p> <p>9 THE VIDEOGRAPHER: Yes.</p> <p>10 MR. KERNER: Yes.</p> <p>11 MS. GEMAN: Yes.</p> <p>12 MS. LOTMAN: Thanks.</p> <p>13 Good afternoon, Dr. Kaplan. Can you hear</p> <p>14 me and see me okay?</p> <p>15 THE WITNESS: I can hear you. You're a little</p> <p>16 picture up there, yeah.</p> <p>17 MS. LOTMAN: It might be better that way.</p> <p>18 THE WITNESS: I'd rather not look at myself</p> <p>19 so.</p> <p>20 MS. LOTMAN: I understand that feeling.</p> <p>21 Happens to me a lot when I'm on Zoom.</p> <p>22 A few questions for you then, Doctor.</p> <p>23</p> <p>24</p>

<p style="text-align: right;">Page 106</p> <p>1 CROSS EXAMINATION</p> <p>2 BY MS. LOTMAN:</p> <p>3 Q. How long did it take for you to develop this</p> <p>4 plan, medical monitoring plan in your report?</p> <p>5 A. I would say about -- about a month, three or</p> <p>6 four weeks.</p> <p>7 Q. Okay. And over the course of that time how</p> <p>8 many -- how many hours do you think you actually spent on</p> <p>9 it?</p> <p>10 A. It should be documented. I think it was</p> <p>11 probably about 12 to -- probably about 20 hours.</p> <p>12 Q. Okay. And that includes -- does that include</p> <p>13 reviewing literature?</p> <p>14 A. Yes.</p> <p>15 Q. And writing the report itself?</p> <p>16 A. Correct.</p> <p>17 Q. How long do you think it took you to actually</p> <p>18 formulate your opinions?</p> <p>19 MS. GEMAN: Objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Ten, twelve hours.</p> <p>22 BY MS. LOTMAN:</p> <p>23 Q. And, Doctor, have you ever -- have you ever</p> <p>24 crafted a medical monitoring plan such as this for</p>	<p style="text-align: right;">Page 108</p> <p>1 BY MS. LOTMAN:</p> <p>2 Q. Let me reask it --</p> <p>3 A. Okay.</p> <p>4 Q. -- because I think it's a little unclear.</p> <p>5 You have patients who have cancer at your practice;</p> <p>6 right?</p> <p>7 A. Correct.</p> <p>8 Q. Do you have patients who have certain genetic</p> <p>9 issues or mutations or elements that you are concerned</p> <p>10 about like BRCA?</p> <p>11 A. Do I -- I couldn't hear you.</p> <p>12 Q. You also treat -- sorry. You also treat</p> <p>13 patients who have certain genetics like BRCA that you</p> <p>14 treat as well, you're monitoring?</p> <p>15 A. Yes.</p> <p>16 Q. Are there any other types of patients that</p> <p>17 you see?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. What are they or who are they?</p> <p>20 A. You want their names and phone numbers?</p> <p>21 Q. No, Doctor. I'm just looking for what is</p> <p>22 their concern that they're seeing an oncologist.</p> <p>23 A. So I happen to have a handful of patients</p> <p>24 that do not see me for oncology, that see me for internal</p>
<p style="text-align: right;">Page 107</p> <p>1 litigation before?</p> <p>2 A. No.</p> <p>3 Q. Have you ever published on medical</p> <p>4 monitoring?</p> <p>5 A. I have not.</p> <p>6 Q. Then, Doctor, you talked before about you</p> <p>7 have your private practice. You have patients who are</p> <p>8 asymptomatic but they have certain genetic issues like</p> <p>9 BRCA; right?</p> <p>10 A. Correct.</p> <p>11 Q. And so you are conducting additional</p> <p>12 monitoring because of that genetic issue; right?</p> <p>13 A. Correct.</p> <p>14 Q. Okay. For patients who -- do you see any</p> <p>15 other patients who are asymptomatic who don't have</p> <p>16 genetic issues?</p> <p>17 A. Could you -- could you rephrase it? Do I see</p> <p>18 any patients?</p> <p>19 Q. Sure. Sure. So do you also have any other</p> <p>20 patients who treat with you who are asymptomatic but did</p> <p>21 not have a prior cancer who do not have genetic issues?</p> <p>22 MS. GEMAN: Objection, vague.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Do I have --</p>	<p style="text-align: right;">Page 109</p> <p>1 medicine either because they were related to a member of</p> <p>2 the family that I took care of or I know them from the</p> <p>3 community or from other people, so I do have some general</p> <p>4 internal medicine patients but not very many. I don't</p> <p>5 consider myself a general internist, but you have to be</p> <p>6 to some degree a general internist in order to be a</p> <p>7 medical oncologist. I do see patients that have had</p> <p>8 abnormal findings, for example, Barrett's esophagus</p> <p>9 or -- well, we mentioned genetic like Lynch syndrome,</p> <p>10 people have had multiple polyps that haven't been</p> <p>11 identified as having a genetic -- a genetic condition</p> <p>12 that's been identified. I do follow patients that have</p> <p>13 had variants of the genetic -- like the BRCA that are</p> <p>14 variants of uncertain significance and so they'll be</p> <p>15 monitored to a certain degree, not the same as a known</p> <p>16 deleterious mutation or known risk mutation but the</p> <p>17 possibility that it is going to be identified as one, so</p> <p>18 they're -- they're followed, and then other patients are</p> <p>19 just concerned. I've had people come in that are just</p> <p>20 concerned about their cancer risk, and I also take care</p> <p>21 of some patients with blood disorders.</p> <p>22 Q. Okay. Doctor, for your patients who smoke,</p> <p>23 you follow the USPSTF guidelines for screening?</p> <p>24 A. I do.</p>

<p style="text-align: right;">Page 110</p> <p>1 Q. Are you aware that tobacco is a known human 2 carcinogen? 3 A. I am. 4 Q. Okay. And you don't recommend any extra 5 screening for those patients who have exposures to 6 tobacco? 7 A. No, I do. I -- I recommend a number of 8 screening procedures for them, mostly the things we've 9 outlined before -- the annual exams or blood tests, urine 10 tests. 11 Q. But you don't go to the same specialized plan 12 that you do for the patients in this case? 13 MS. GEMAN: Objection. 14 BY THE WITNESS: 15 A. I have not developed a specialized program 16 for that group of patients at this time. 17 BY MS. LOTMAN: 18 Q. So you treat patients who have exposure to 19 tobacco, a known human carcinogen, and you don't 20 recommend that they have the same types of tests, the 21 specialized testing that you've recommended for the 22 patients who have alleged exposure to nitrosamines? 23 MS. GEMAN: Objection, misstates the 24 testimony.</p>	<p style="text-align: right;">Page 112</p> <p>1 A. Not yet, no. But many tests that we do don't 2 have FDA approval, blood tests in the office, other 3 things, but yeah, you're right. It does not yet have FDA 4 approval. They're attempting to get FDA approval. 5 Q. Doctor, do you know the difference between a 6 known human carcinogen and a probable human carcinogen? 7 A. I'm assuming a known human carcinogen has 8 been proven to cause cancer. Usually -- I mean in humans 9 most of the probable human carcinogens are based on 10 animal studies and epidemiologic studies. 11 Q. Okay. Do you know what a probable human 12 carcinogen is? 13 A. So I'm saying probable is something that's 14 been shown in, probably in animal studies to increase 15 risk of cancer and to suggest that there's a human risk 16 as well. 17 Q. Suggest not -- not a -- not know? 18 A. I'm sorry? 19 Q. You said suggest and probable; right, for the 20 probable one? There's not a known carcinogen? There's a 21 difference; right? 22 A. Well, known human carcinogen may be a proven 23 carcinogen in the laboratory or in animal studies. 24 Q. Okay. Would you make the same about say</p>
<p style="text-align: right;">Page 111</p> <p>1 BY THE WITNESS: 2 A. I don't have a class program for those 3 patients I've -- that I've recommended. I don't have 4 large enough numbers that I'm seeing, and I haven't been 5 asked to do that. 6 BY MS. LOTMAN: 7 Q. So for your patients who smoke, you don't 8 have them go through the Galleri? They don't have 9 Galleri testing, do they? 10 A. No, but that's something that I intend to 11 start doing. 12 Q. When do you intend to start doing that? 13 A. Soon. I've already ordered the test a few 14 times. I've recently learned about the test and 15 evaluated its usefulness and have learned more about it, 16 and so I'm starting to order it or recommend it for 17 patients. 18 Q. How do you order it? 19 A. It's a prescription. It's a kit. You draw 20 blood and you send it off in a kit to the company. 21 Q. Does Galleri currently have FDA approval? 22 A. Galleri does not yet have FDA approval. It 23 does have CLIA certification. 24 Q. But does not have FDA approval?</p>	<p style="text-align: right;">Page 113</p> <p>1 medical monitoring for a probable human carcinogen as you 2 would for a known human carcinogen? 3 MS. GEMAN: Objection, incomplete 4 hypothetical. 5 BY THE WITNESS: 6 A. I haven't thought of that, so I don't have an 7 answer. 8 MS. LOTMAN: Okay. Those are all of my 9 questions. 10 Thank you very much for your time, Doctor. 11 THE WITNESS: Sure. 12 MR. KERNER: Anybody else have any questions? 13 (No response.) 14 Well, if nobody else has any questions, I 15 do very quickly. 16 I just want to mark another exhibit. 17 (Exhibit No. 5 marked as 18 requested.) 19 MS. GEMAN: This is 5. 20 MR. KERNER: This is 5. For the Zoom folks, 21 it says "Invoices." 22 MS. GEMAN: So in my copy it's three -- yeah, 23 it's three identical pages of October 22nd. 24 THE WITNESS: I have the same thing. Oh, it's</p>

<p style="text-align: right;">Page 114</p> <p>1 October 7th -- I mean November 7th to November 10th.</p> <p>2 MR. KERNER: Okay. Let's do it this way.</p> <p>3 MS. ISIDRO: Go off the record.</p> <p>4 MR. KERNER: Yeah. Let's go off the record</p> <p>5 for a second.</p> <p>6 THE VIDEOGRAPHER: The time now is 12:15.</p> <p>7 This is the end of media five. We're off the record.</p> <p>8 (WHEREUPON, a break was</p> <p>9 taken.)</p> <p>10 The time is 12:17 p.m. This is the</p> <p>11 beginning of media six. We're back on the record.</p> <p>12 REDIRECT EXAMINATION</p> <p>13 BY MR. KERNER:</p> <p>14 Q. Okay, Doctor. We just wanted to mark Exhibit</p> <p>15 5 and talk about them real quickly. Can you tell us what</p> <p>16 Exhibit 5 is?</p> <p>17 A. My invoices to -- to the lawyers.</p> <p>18 Q. And how many invoices are there?</p> <p>19 A. There are four in front of me.</p> <p>20 Q. Okay. And they're all addressed to Nicholas</p> <p>21 Migliaccio?</p> <p>22 A. Correct.</p> <p>23 Q. Does that sound right?</p> <p>24 A. Correct.</p>	<p style="text-align: right;">Page 116</p> <p>1 BY MR. KERNER:</p> <p>2 Q. Okay. Fair enough. So you -- on October</p> <p>3 22nd, 2001 you sent an invoice for a retainer of \$2,000?</p> <p>4 MS. GEMAN: 2021 not 2001.</p> <p>5 MR. KERNER: Oh, gosh, yeah. October 22nd,</p> <p>6 2021.</p> <p>7 MS. GEMAN: We're not that slow.</p> <p>8 BY MR. KERNER:</p> <p>9 Q. And that was for \$2,000; correct?</p> <p>10 A. Correct.</p> <p>11 Q. Has that been paid?</p> <p>12 A. Yes.</p> <p>13 Q. And then the next invoice is November 5th,</p> <p>14 2021 and that looks to be for time spent from</p> <p>15 October 20th to November 5th, and you spent 20 hours</p> <p>16 during that time frame for teleconferences and</p> <p>17 communication, review of literature, analyses and report</p> <p>18 review; correct?</p> <p>19 A. Correct.</p> <p>20 Q. Okay. And you billed that out at \$450 an</p> <p>21 hour?</p> <p>22 A. Correct.</p> <p>23 Q. And so the invoice is for \$11,250; correct?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. Who is that?</p> <p>2 A. It's the attorney that is -- one of the</p> <p>3 attorneys involved in this case.</p> <p>4 Q. Okay. But he's not the one who contacted you</p> <p>5 initially?</p> <p>6 A. No, I think he's the first one that I spoke</p> <p>7 to or one of the first ones that I spoke to. I can't</p> <p>8 recall.</p> <p>9 Q. Okay. So it was not at Lieff Cabraser as you</p> <p>10 testified earlier?</p> <p>11 MS. GEMAN: Objection, misstates testimony.</p> <p>12 BY THE WITNESS:</p> <p>13 A. She's one of the attorneys also that I -- I</p> <p>14 didn't remember who it was that contacted me first, but</p> <p>15 she's one that's been on all of our meetings.</p> <p>16 BY MR. KERNER:</p> <p>17 Q. But Mr. Migliaccio was the first one to</p> <p>18 contact you?</p> <p>19 MS. GEMAN: Objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. I don't recall exactly who was the first one</p> <p>22 to contact. That's the one who I was told to send the</p> <p>23 invoices to.</p> <p>24</p>	<p style="text-align: right;">Page 117</p> <p>1 Q. Was that paid?</p> <p>2 A. Yes, I believe so.</p> <p>3 Q. And the third invoice is five days later</p> <p>4 dated November 10th, and that was for time spent from</p> <p>5 November 7th to November 10th of 2021; correct?</p> <p>6 A. Correct.</p> <p>7 Q. And that also was for teleconferences and</p> <p>8 communication, review of literature, analyses and report</p> <p>9 review and writing and correcting reports; correct?</p> <p>10 A. Correct.</p> <p>11 Q. And you spent 11 hours?</p> <p>12 A. Correct.</p> <p>13 Q. Also billed out at \$450 an hour. I guess</p> <p>14 there's a .25 percent charge added onto it?</p> <p>15 A. Right.</p> <p>16 Q. What's that?</p> <p>17 A. It was because it was -- there was a time</p> <p>18 limit. It was rushed, not rushed, but there was a</p> <p>19 deadline to get it in, so I had to work within a shorter</p> <p>20 time frame.</p> <p>21 Q. Got it. And, by the way, the prior invoice</p> <p>22 on November 5th had that same --</p> <p>23 A. Correct.</p> <p>24 Q. -- .25 percent?</p>

<p style="text-align: right;">Page 118</p> <p>1 A. Correct.</p> <p>2 Q. So this third invoice was for \$6,187.50, also</p> <p>3 billed out at \$450 an hour; correct?</p> <p>4 A. Correct.</p> <p>5 Q. And the final invoice that we have is dated</p> <p>6 December 31st, 2021 for time spent from December 16th to</p> <p>7 December 31st for teleconference and review of records;</p> <p>8 correct?</p> <p>9 A. Correct.</p> <p>10 Q. What records did you review?</p> <p>11 A. I don't know the exact records. It's all the</p> <p>12 references that we had. It was discussing my report with</p> <p>13 the lawyers. I can't remember specifically.</p> <p>14 Q. Okay. And you spent 11 hours according to</p> <p>15 the invoice?</p> <p>16 A. Correct.</p> <p>17 Q. And there was no .25 percent charge on this</p> <p>18 one; correct?</p> <p>19 A. Correct.</p> <p>20 Q. And so the total amount due was 5500?</p> <p>21 A. Correct.</p> <p>22 Q. Has that been paid?</p> <p>23 A. I don't think so. I don't -- I don't</p> <p>24 remember.</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. An extra 50 bucks an hour?</p> <p>2 A. Yeah.</p> <p>3 MR. KERNER: Okay. That's all I have.</p> <p>4 THE WITNESS: Okay.</p> <p>5 MR. KERNER: Anybody else has anything, speak</p> <p>6 now.</p> <p>7 MR. GEOPPINGER: Yeah, I have a couple</p> <p>8 questions, if I may. Good afternoon, Doctor. My name is</p> <p>9 Jeff Geoppinger. I'm here on behalf of Amerisource</p> <p>10 Bergen. Can you see me now?</p> <p>11 THE WITNESS: Sort of, yes.</p> <p>12 MR. GEOPPINGER: Good afternoon. Again, my</p> <p>13 name is Jeff Geoppinger. I represent Amerisource Bergen</p> <p>14 in this litigation. I just have a real quick couple</p> <p>15 follow-up questions.</p> <p>16 CROSS EXAMINATION</p> <p>17 BY MR. GEOPPINGER:</p> <p>18 Q. Earlier when you were talking to Ms. Lotman,</p> <p>19 you mentioned you have patients who you treat who are</p> <p>20 just concerned about cancer risk. Did I hear that</p> <p>21 correctly?</p> <p>22 A. Yes.</p> <p>23 Q. Are those patients asymptomatic?</p> <p>24 A. I think many of them are. There aren't a lot</p>
<p style="text-align: right;">Page 119</p> <p>1 Q. Okay. So -- so overall it looks as though</p> <p>2 you spent 44 hours --</p> <p>3 A. Okay.</p> <p>4 Q. -- correct?</p> <p>5 And you charged approximately \$24,000 and</p> <p>6 change; correct?</p> <p>7 A. Okay. I hadn't added it up.</p> <p>8 Q. Will you be providing any additional invoices</p> <p>9 for time since December 31st?</p> <p>10 A. Yes.</p> <p>11 Q. Do you have any idea how many hours you've</p> <p>12 spent since then?</p> <p>13 A. In preparing for the deposition, probably</p> <p>14 another 20 hours --</p> <p>15 Q. And --</p> <p>16 A. -- including the deposition.</p> <p>17 Q. Including the deposition.</p> <p>18 Okay. And I think you told us your rate for</p> <p>19 the deposition was \$600 an hour?</p> <p>20 A. Correct.</p> <p>21 Q. By the way, I note that on the last invoice</p> <p>22 dated December 31st you billed 11 hours at \$500 an hour,</p> <p>23 so your rate went up from November 10th to December 16th?</p> <p>24 A. Inflation.</p>	<p style="text-align: right;">Page 121</p> <p>1 of them in that category, but there are some who are</p> <p>2 asymptomatic.</p> <p>3 Q. I understand. They don't have an active</p> <p>4 cancer diagnosis; correct?</p> <p>5 A. Correct.</p> <p>6 Q. And they don't have any genetic conditions</p> <p>7 that would predispose them to cancer that they're</p> <p>8 concerned about or that you're concerned about; correct?</p> <p>9 A. None that had been identified, yes.</p> <p>10 Q. Okay. So for those patients, what do you do</p> <p>11 to treat them?</p> <p>12 A. So they're not being treated. They're being</p> <p>13 monitored, and it includes basic -- basic exam, something</p> <p>14 they may get from their internist but with more focus on</p> <p>15 cancers.</p> <p>16 Q. And is that screening the same for all of</p> <p>17 those patients or does it vary by, you know, individual</p> <p>18 patient?</p> <p>19 A. The basic screening is the same for all of</p> <p>20 them because they need to have a good exam, they need to</p> <p>21 have basic laboratory tests, and they need a good</p> <p>22 history, and I'm finding many of them aren't getting</p> <p>23 those things done in their general practices, in the</p> <p>24 primary practice because of very busy doctors, so I'll be</p>

<p style="text-align: right;">Page 122</p> <p>1 a little more -- I'll take longer, and I'll be a little</p> <p>2 more detailed, but everybody will get a basic screening.</p> <p>3 If there's anything discovered, then they would go on to</p> <p>4 get more unique tests done.</p> <p>5 Q. I'm sorry. I didn't hear the end of that</p> <p>6 answer. What was that you said, Doctor?</p> <p>7 A. They're all screened the same way. That's</p> <p>8 what I wanted to say.</p> <p>9 Q. Okay. And do -- after the basic screening</p> <p>10 that they all get the same way do some of those patients</p> <p>11 get additional screening based upon what you find after</p> <p>12 you do the basic screening?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And do they all get the same</p> <p>15 additional screening or does it vary by patient?</p> <p>16 A. It would vary by what the reason is for doing</p> <p>17 the additional screening.</p> <p>18 Q. Okay. Now I'm going to ask you a</p> <p>19 hypothetical. If one of those asymptomatic patients</p> <p>20 provided you information that they had -- they ate a lot</p> <p>21 of bacon or that they had taken Valsartan between 2012</p> <p>22 and 2018, would your screening of that patient change in</p> <p>23 any way?</p> <p>24 MS. GEMAN: Objection, incomplete</p>	<p style="text-align: right;">Page 124</p> <p>1 MS. GEMAN: Objection, asked and answered,</p> <p>2 incomplete hypothetical, vague.</p> <p>3 BY THE WITNESS:</p> <p>4 A. The Valsartan is not -- is not a deal -- a</p> <p>5 detail that I can answer to because the patients we're</p> <p>6 dealing with have levels that have been proven, have been</p> <p>7 identified to be in a class. You're talking about an</p> <p>8 individual person who's taking the drug. I wouldn't have</p> <p>9 any -- right now any -- a plan of how to specifically</p> <p>10 address that patient. They would need the same</p> <p>11 monitoring and the same -- I mean the same evaluation</p> <p>12 that the patients in the class have had to determine</p> <p>13 their level of -- of exposure, et cetera.</p> <p>14 BY MR. GEOPPINGER:</p> <p>15 Q. Would it be accurate to say you would treat</p> <p>16 that patient just like you do the asymptomatic patients</p> <p>17 you treat now?</p> <p>18 MS. GEMAN: Objection.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Again, it depends on -- on the situation of</p> <p>21 the patient that I have in front of me. To take one</p> <p>22 patient is very difficult to answer. It's not a real</p> <p>23 patient.</p> <p>24</p>
<p style="text-align: right;">Page 123</p> <p>1 hypothetical, compound.</p> <p>2 BY THE WITNESS:</p> <p>3 A. It would depend. I'd have to be there with</p> <p>4 the patient and see -- hear everything about it. I can't</p> <p>5 answer that question with what you've told me.</p> <p>6 BY MR. GEOPPINGER:</p> <p>7 Q. Would it be accurate to say that you would</p> <p>8 make an individual determination about the screening in</p> <p>9 that case --</p> <p>10 MS. GEMAN: Objection.</p> <p>11 BY MR. GEOPPINGER:</p> <p>12 Q. -- for the patient?</p> <p>13 A. After the initial evaluation I would make an</p> <p>14 independent decision just like with any patient including</p> <p>15 Valsartan-exposed patients after they've gone through the</p> <p>16 screening I've recommended.</p> <p>17 Q. Okay. So in my hypothetical I have an</p> <p>18 asymptomatic patient who tells you that they have -- that</p> <p>19 they had foods in their diet that may include NDMA, that</p> <p>20 they may have been taking Valsartan-containing products</p> <p>21 from 2012 to 2018. In that situation, would your process</p> <p>22 for treating an asymptomatic patient be any different</p> <p>23 than it would be in treating the asymptomatic patients</p> <p>24 you see right now?</p>	<p style="text-align: right;">Page 125</p> <p>1 BY MR. GEOPPINGER:</p> <p>2 Q. Would you give -- would you recommend for</p> <p>3 that patient who reveals to you the -- their history of</p> <p>4 dietary intake of NDMA and potential history of VCB usage</p> <p>5 and NDMA, would you automatically screen them for all the</p> <p>6 conditions that you've listed in your report?</p> <p>7 MS. GEMAN: Objection, incomplete</p> <p>8 hypothetical.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Just on the basis of that history I wouldn't</p> <p>11 necessarily do anything different than what we've already</p> <p>12 discussed.</p> <p>13 MR. GEOPPINGER: Thank you, Doctor. I don't</p> <p>14 have any further questions.</p> <p>15 MR. KERNER: Anyone else?</p> <p>16 MS. LOTMAN: If I may, Doctor. This is Alyson</p> <p>17 Lotman. I have one more question. I think it's just</p> <p>18 one.</p> <p>19 RECROSS EXAMINATION</p> <p>20 BY MS. LOTMAN:</p> <p>21 Q. Who do you recommend to do these screenings?</p> <p>22 MS. GEMAN: Objection.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I don't understand your question. Who do I</p>

<p style="text-align: right;">Page 126</p> <p>1 recommend?</p> <p>2 BY MS. LOTMAN:</p> <p>3 Q. If these -- if the patients were to get the</p> <p>4 screening that you recommended here, who should be</p> <p>5 administering it?</p> <p>6 A. Well, as I outlined in my report, it would be</p> <p>7 either the primary care doctor or an oncologist or a</p> <p>8 general practitioner, a family practitioner, somebody</p> <p>9 that would be made aware usually through the patient</p> <p>10 telling them that they have this exposure, this risk and</p> <p>11 they have this recommended guideline for screening.</p> <p>12 Q. And if their doctor decided that based upon</p> <p>13 their comorbidities or their medical history that these</p> <p>14 were unnecessary, do you believe that your plan should</p> <p>15 stand in place of that doctor's judgment?</p> <p>16 MS. GEMAN: Objection, incomplete</p> <p>17 hypothetical.</p> <p>18 BY THE WITNESS:</p> <p>19 A. My plan is a guideline, just like the NCCN</p> <p>20 has their guidelines, and it's up to the individual</p> <p>21 practitioner to -- to decide based on the individual</p> <p>22 patient what is appropriate for them.</p> <p>23 MS. LOTMAN: Thank you very much, Doctor.</p> <p>24 MS. GEMAN: Are there any other questions from</p>	<p style="text-align: right;">Page 128</p> <p>1 You're not recommending that this monitoring program be</p> <p>2 provided to people who did not take the contaminated</p> <p>3 Valsartan, i.e. you are not recommending this program to,</p> <p>4 this exact program to non-class members; correct?</p> <p>5 A. The point of this program was medical</p> <p>6 monitoring for those that had been identified as being at</p> <p>7 risk because of their intake of Valsartan-contaminated</p> <p>8 products.</p> <p>9 MS. GEMAN: Okay. Thank you for the</p> <p>10 clarification.</p> <p>11 Okay. We'd like to read and sign.</p> <p>12 MR. KERNER: Yeah.</p> <p>13 THE VIDEOGRAPHER: The time is now 12:33 p.m.</p> <p>14 This is the end of media six.</p> <p>15 This concludes this deposition. We're off</p> <p>16 the record.</p> <p>17 THE REPORTER: Would anyone like a copy of the</p> <p>18 transcript?</p> <p>19 MR. STOY: This is Frank Stoy. I'd like an</p> <p>20 electronic copy, please.</p> <p>21 MS. LOTMAN: Alyson Lotman. I'd like the</p> <p>22 same.</p> <p>23 MR. CHARCHALIS: (Inaudible).</p> <p>24 MS. ISIDRO: Mitchell wants an electronic.</p>
<p style="text-align: right;">Page 127</p> <p>1 the Defendants?</p> <p>2 (No response.)</p> <p>3 Do you have it on your screen? Did people</p> <p>4 write in?</p> <p>5 MS. ISIDRO: No one else on the Zoom?</p> <p>6 MS. GEMAN: Do you formally conclude it and</p> <p>7 pass it to me? How are we doing this?</p> <p>8 MR. KERNER: Yeah, if none of the Defendants</p> <p>9 have any questions and you have questions, ask away.</p> <p>10 MS. GEMAN: Thank you.</p> <p>11 CROSS EXAMINATION</p> <p>12 BY MS. GEMAN:</p> <p>13 Q. Dr. Kaplan, what is CLIA certification?</p> <p>14 A. CLIA certification is -- is certification</p> <p>15 that's given by a board that -- that attests to the</p> <p>16 accuracy and the usefulness of a particular test, that</p> <p>17 it's considered accurate and it does have some impact for</p> <p>18 the patient.</p> <p>19 Q. Okay. Can you please take out what's been</p> <p>20 marked as Exhibit 3 and turn to Page 3. Does the class</p> <p>21 as set forth on Page 3 capture the population of people</p> <p>22 for whom you are recommending your monitoring program?</p> <p>23 A. Yes.</p> <p>24 Q. I think there was some confusion before.</p>	<p style="text-align: right;">Page 129</p> <p>1 STATE OF ILLINOIS)</p> <p>2) SS:</p> <p>3 COUNTY OF C O O K)</p> <p>4 I, KELLY A. BRICHETTO, a Certified Shorthand</p> <p>5 Reporter of said state, do hereby certify</p> <p>6 that the within named witness, EDWARD H. KAPLAN, M.D.,</p> <p>7 was by me first duly sworn to testify the truth, the</p> <p>8 whole truth and nothing but the truth in the cause</p> <p>9 aforesaid; that the testimony then given by the</p> <p>10 above-referenced witness was by me reduced to stenotype</p> <p>11 in the presence of said witness; afterwards transcribed,</p> <p>12 and that the foregoing is a true and correct</p> <p>13 transcription of the testimony so given by the</p> <p>14 above-referenced witness.</p> <p>15 I do further certify that this deposition was</p> <p>16 taken at the time and place in the foregoing caption</p> <p>17 specified and was completed without adjournment.</p> <p>18 I do further certify that I am not a relative,</p> <p>19 counsel or attorney for either party or otherwise</p> <p>20 interested in the event of this action.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

<p style="text-align: right;">Page 130</p> <p>1 IN WITNESS WHEREOF, I do hereunto set my hand</p> <p>2 this 21st day of January, 2022.</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7 <i>Kelly Brichetto</i></p> <p>8 KELLY A. BRICHETTO</p> <p>9 CSR License No. 84-3252</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 132</p> <p>1 In Re: Valsartan, Losartan, Et Al v.</p> <p>2 Edward H Kaplan , MD (#5025121)</p> <p>3 E R R A T A S H E E T</p> <p>4 PAGE_____ LINE_____ CHANGE_____</p> <p>5 _____</p> <p>6 REASON_____</p> <p>7 PAGE_____ LINE_____ CHANGE_____</p> <p>8 _____</p> <p>9 REASON_____</p> <p>10 PAGE_____ LINE_____ CHANGE_____</p> <p>11 _____</p> <p>12 REASON_____</p> <p>13 PAGE_____ LINE_____ CHANGE_____</p> <p>14 _____</p> <p>15 REASON_____</p> <p>16 PAGE_____ LINE_____ CHANGE_____</p> <p>17 _____</p> <p>18 REASON_____</p> <p>19 PAGE_____ LINE_____ CHANGE_____</p> <p>20 _____</p> <p>21 REASON_____</p> <p>22 _____</p> <p>23 _____</p> <p>24 Edward H Kaplan , MD Date</p>
<p style="text-align: right;">Page 131</p> <p>1 RACHEL J. GEMAN</p> <p>2 rgeman@lchb.com</p> <p>3 January 26, 2022</p> <p>4 RE: In Re: Valsartan, Losartan, Et Al</p> <p>5 1/19/2022, Edward H Kaplan , MD (#5025121)</p> <p>6 The above-referenced transcript is available for</p> <p>7 review.</p> <p>8 Within the applicable timeframe, the witness should</p> <p>9 read the testimony to verify its accuracy. If there are</p> <p>10 any changes, the witness should note those with the</p> <p>11 reason, on the attached Errata Sheet.</p> <p>12 The witness should sign the Acknowledgment of</p> <p>13 Deponent and Errata and return to the deposing attorney.</p> <p>14 Copies should be sent to all counsel, and to Veritext at</p> <p>15 erratas-cs@veritext.com</p> <p>16</p> <p>17 Return completed errata within 30 days from</p> <p>18 receipt of testimony.</p> <p>19 If the witness fails to do so within the time</p> <p>20 allotted, the transcript may be used as if signed.</p> <p>21</p> <p>22 Yours,</p> <p>23 Veritext Legal Solutions</p> <p>24</p>	<p style="text-align: right;">Page 133</p> <p>1 In Re: Valsartan, Losartan, Et Al v.</p> <p>2 Edward H Kaplan , MD (#5025121)</p> <p>3 ACKNOWLEDGEMENT OF DEPONENT</p> <p>4 I, Edward H Kaplan , MD, do hereby declare that I</p> <p>5 have read the foregoing transcript, I have made any</p> <p>6 corrections, additions, or changes I deemed necessary as</p> <p>7 noted above to be appended hereto, and that the same is</p> <p>8 a true, correct and complete transcript of the testimony</p> <p>9 given by me.</p> <p>10 _____</p> <p>11 _____</p> <p>12 Edward H Kaplan , MD Date</p> <p>13 *If notary is required</p> <p>14 SUBSCRIBED AND SWORN TO BEFORE ME THIS</p> <p>15 _____ DAY OF _____, 20____.</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 NOTARY PUBLIC</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

[& - 75201]

Page 1

&	17th 4:15	2200 3:21	4
& 2:3,9,21 4:8,19 5:2,8	19 1:9,16	22nd 113:23 116:3 116:5	4 6:4 7:6 74:8 86:13 90:13 97:9 103:21,23
0	19087 3:4	24,000 119:5	412 2:9
02109 4:10	19103 4:16	25 17:5 117:14,24 118:17	423 4:5
1	1982 37:2	250 2:4	44 7:5 119:2
1 7:3 28:14,16,23 47:14,15,17 48:3,4 48:5 60:17	1983 37:17	2500 3:16	450 116:20 117:13 118:3
1,000 48:18	1985 37:18,19	26 131:3	45202 5:4
1.05 91:2	1988 37:19,21 38:10	260 2:16	470-3520 2:11
1/19/2022 131:5	1995 39:8	270 3:4	5
10013 2:5	19th 8:4	27th 4:9	5 7:7 86:19 91:11 113:17,19,20 114:15,16
10017 3:10	1c 93:23	2800 5:3	50 54:11 120:1
104 7:6	2	2875 1:3	50/50 23:6
107 6:8	2 6:2 7:4 36:2,3,7 48:20 64:7 86:14	29 7:3	500 62:9 119:22
10:21 60:8	2,000 116:3,9	3	5025121 131:5 132:2 133:2
10:39 60:12	20 13:6,8 106:11 116:15 119:14 133:15	3 7:5 43:15,16,19 55:8 66:1,15 79:20 127:20,20 127:21	513 5:4
10th 114:1 117:4,5 119:23	20,000 96:21	3,000 48:19	53 4:9
11 6:7 117:11 118:14 119:22	200 3:15	3.3 91:2	550 3:3
11,250 116:23	20002 2:10	30 4:15 131:17	5500 118:20
115 6:9 7:7	2001 116:3,4	30,000 96:21	5th 116:13,15 117:22
11:34 99:6	2012 122:21 123:21	300 4:4 5:9	6
11:56 99:10	2018 122:22 123:21	301 4:21	6 30:19 71:15 94:2 94:2
12 106:11	202 2:11	302 2:10	6,187.50 118:2
121 6:10	2021 34:6 116:4,6 116:14 117:5 118:6	30305 3:16	600 2:22 5:3 62:11 62:12 119:19
12498 130:6	2022 1:9,17 8:4 130:2 131:3	3100 1:16	60076 24:10
126 6:11	2029 5:9	316 2:21	617 4:10
128 6:12	20th 116:15	31st 118:6,7 119:9 119:22	66210 2:16
12:15 114:6	212 2:5 3:10	32501 2:22	698-5000 5:4
12:17 114:10	213-7045 4:10	3333 3:15	7
12:33 128:13	214 3:22	355-9500 2:5	736 4:3
13 30:9,13 31:23	215 3:5 4:16	3600 3:21	75201 3:22
131 6:14	21st 130:2	37 7:4	
15 22:5		37402 4:4	
15219 4:23		385-5400 2:17	
16th 118:6 119:23		38th 4:22	

[755-2652 - answered]

Page 2

755-2652 4:5 77 1:15 8:6 7th 114:1,1 117:5	account 52:14 89:20 accuracy 127:16 131:9 accurate 30:24 123:7 124:15 127:17 achieved 85:9 89:2 acknowledgement 133:3 acknowledgment 131:12 acquire 38:16 action 129:19 active 121:3 activities 54:9,12 actual 97:2 acute 26:22 27:8 27:17,19 added 117:14 119:7 addition 35:13 92:20 additional 58:15 70:21 107:11 119:8 122:11,15 122:17 additions 133:6 address 24:8 44:1 44:3 124:10 addressed 114:20 addressing 95:20 101:3 adenomatous 97:19 adjournment 129:16 administered 27:13 64:14 administering 126:5	adriamycin 75:11 advance 11:23 advised 41:22 aforesaid 129:8 afternoon 10:15 105:13 120:8,12 agencies 50:14 agents 19:6,12,14 19:17,21,24 101:2 aggressive 55:2 56:23 57:1,21 72:21 ago 10:11 12:6 13:6,8 17:5 21:9 29:3 33:22 34:2,4 34:8 44:8,9 49:5 agree 34:23 83:6 95:22 agreed 34:22 95:23 ahead 41:7 ahh 37:20 aid 5:7 al 8:8 131:4 132:1 133:1 alberto 3:2 alfano 4:19 algorithm 51:6 algorithms 50:22 alleged 110:22 allotted 131:20 allow 38:20 42:13 42:16 72:14 88:1 allowing 38:15 allows 44:11 alluded 57:20 74:5 alotman 4:17 alyson 4:14 104:22 104:24 105:3 125:16 128:21	american 87:21 amerisource 5:1 120:9,13 amount 74:19 75:2 76:15,22 78:18 118:20 amounts 42:9 analyses 116:17 117:8 analysis 42:22 43:10 45:14 74:9 andrew 3:2 andrew.alberto 3:5 anemia 25:18 anesthesia 49:16 angeles 5:10 animal 112:10,14 112:23 annual 45:15,23 46:20 47:1,5 48:24 49:6,14,17 50:11 86:23 87:2 87:10,20 88:8 92:18 110:9 annually 52:20 61:8 86:19 87:5 90:9 answer 11:2,10,17 15:5 46:13,13 48:7 61:13 64:23 69:23 82:22 99:3 101:8 103:5 113:7 122:6 123:5 124:5 124:22 answer's 74:6 96:14 answered 41:20 67:24 88:11,12 92:7 96:15 100:20 124:1
8			
80 71:24 72:16,18 801-9200 3:10 8101 2:15 84-3252 130:8 85 72:3,5 855-8000 3:22 8th 2:4			
9			
9 24:9 90 73:3 90067 5:10 913 2:17 9631 24:9 977-4058 3:5 979-1177 4:16 9:14 1:10,17 8:5 9:15 9:12 9:16 9:16 9:41 32:7 9:43 32:11			
a			
a.m. 1:10,17 8:5 9:16 32:7,11 60:8 60:12 99:6,10 ability 88:2 95:4 able 19:9,10 abnormal 109:8 abnormalities 45:1,4 61:22 abnormality 45:9 absence 80:9 82:4 82:13 abstracts 39:16,23 accepted 54:3 61:8 73:14			

[answering - benefits]

Page 3

answering 46:11 anticipated 26:5 anticipating 53:24 anybody 59:13 84:23 85:9 113:12 120:5 anyway 70:9 api 66:2 apologize 105:5 appearance 105:1 appearances 6:2 appended 133:7 applicable 131:8 appreciate 46:15 87:9 89:22 approached 32:18 appropriate 42:17 46:24 51:18,19 52:15,16,20 55:5 64:15 65:8,10 71:15,19 83:2 90:1 92:21 98:2 100:18 101:11 126:22 approval 111:21 111:22,24 112:2,4 112:4 approximately 1:17 8:5 12:5 119:5 arm 70:15,15 arranged 64:20 articles 35:21,22 aside 22:13 23:18 25:12 49:15 asked 12:24 14:4,4 17:9 18:8 19:3 20:6,19 21:14,15 28:3 30:11 32:20 33:11 34:11 40:10 40:21,23 41:17,20	41:23 43:4,4 44:9 67:24 84:15 88:11 92:7 96:15 99:2 100:20 102:2 104:6 111:5 124:1 asking 10:14 11:13 41:10 96:6 assessed 102:13,15 102:21,23 assessment 53:9 assigned 39:8 assistant 24:17 38:7,9 associate 26:4,6,23 associated 35:1 70:9 74:21 assume 11:18 56:21 64:12 assumed 63:21 74:9 assuming 112:7 assumption 64:1,7 75:22 76:3,4 102:4 assumptions 41:9 63:12,12 74:14,15 assure 45:14 asymptomatic 54:8 58:20 59:5 107:8,15,20 120:23 121:2 122:19 123:18,22 123:23 124:16 ate 122:20 atlanta 3:16 attached 35:22 36:13 131:11 attempting 112:4 attending 38:2 attests 127:15	attorney 10:11 13:19,24 15:14 18:1,20 19:3 29:6 31:14 115:2 129:18 131:13 attorneys 20:10 29:5 40:10 43:22 44:1,1 115:3,13 august 34:10 88:1 auspicious 9:3 authoritative 99:18 100:3,16 101:9 automatically 125:5 available 85:21 131:6 avenue 3:9,21 4:3 aware 32:17 43:18 85:19,21 100:15 101:9 110:1 126:9 awhile 22:5 33:22	66:9,11,19 67:6 68:10 69:13 70:11 71:2 76:4,6 82:21 87:3 90:22,24 91:3 100:11 102:9 102:11,12 112:9 122:11 126:12,21 basic 45:14 57:9 59:7,12 69:11,14 70:12,21 93:24 121:13,13,19,21 122:2,9,12 basically 91:3 basis 51:14 68:4,5 72:15 79:5 125:10 baylen 2:21 began 40:15 beginning 9:4 28:3 32:12 60:13 99:11 114:11 behalf 2:2,7,13,19 3:1,6,12,18 4:1,6 4:12,18 5:1,6 120:9 behoove 69:13 70:4 believe 12:15 13:8 14:15 16:1,13 18:24 23:13 27:9 29:2 30:10 31:12 34:6 36:12 47:14 47:15,18 50:14 54:23 55:20 58:8 62:14 77:4 90:11 91:22 95:4 97:16 98:8 117:2 126:14 ben 5:14 benefit 55:2 benefits 49:23 74:4
--	--	---	---

[benzene - catenacci's]

Page 4

benzene 20:2 bergen 5:1 120:10 120:13 berne 5:2 bernstein 2:3 best 95:3 better 28:10 54:11 105:17 beyond 41:10 69:20 biliary 27:6 bill 87:24 billed 116:20 117:13 118:3 119:22 biopsy 86:19 bit 56:1,22 blackwell 4:3 bladder 93:1,2,5,7 blood 24:22,24 25:7,10,12,19 26:2 26:5 45:14 57:10 71:23 73:11 87:6 93:23 109:21 110:9 111:20 112:2 board 127:15 body 77:22 85:18 bone 25:20 27:21 booklet 11:4 bosick 4:19 boston 4:10 bottom 79:20 boulevard 2:15 bowel 27:6,6 brando 26:9 brca 45:1 60:22 107:9 108:10,13 109:13 break 32:1 60:7,10 73:12 99:5,8	114:8 breast 12:24 22:7 27:2 brett 2:14,17 brichetto 1:14 8:10 129:3 130:7 brief 17:8 briefly 91:22 brisbois 3:3 broad 25:23 brought 87:24 brown 2:19 btlaw.com. 5:10 bucks 120:1 building 24:12 bunch 10:14 39:15 busy 121:24	57:5,6,11,12,13,15 57:18,23 58:8,11 58:18,18 59:15,16 59:20 60:4 61:22 71:14,16,19 72:21 80:3,15,19 81:11 81:13,15 86:22 87:21 88:16,20 90:23 91:2,18,23 92:5,16,21 93:1,3 93:5,11,12,15,20 96:10,23 97:3 98:24 99:1,20 100:5,18 102:1,6 102:18,22 103:9 107:21 108:5 109:20 112:8,15 120:20 121:4,7 cancers 24:24 25:2 25:8,14,15,16 26:15,19 27:4,7,7 27:14 42:2 66:17 67:2,4,5,10,14,16 67:16,20,23 68:6 68:15,23 69:8 74:12,12 86:21 87:14 88:3,15 91:8,14 92:3,12 93:3,9,9 97:5 121:15 candidate 73:24 capable 28:8 caption 129:15 capture 127:21 carcinogen 68:8 110:2,19 112:6,6,7 112:12,20,22,23 113:1,2 carcinogenic 43:10	carcinogenicity 102:14 carcinogens 33:13 33:14 34:12 42:11 66:4 72:19 73:2 112:9 carcinoma 45:17 81:7 cardiovascular 47:6 care 22:7 26:4,22 26:24 27:10 42:15 42:16 44:18 48:18 109:2,20 126:7 career 48:20 96:19 cares 48:22 caring 17:4 carry 45:3 carrying 53:2 case 12:7,11,14,16 12:20 13:2,9 14:5 14:7,8,14,15 15:8 15:10,17 16:6 17:5,15,17,22 18:6 18:12 19:1 20:8 22:13 24:1,2 30:20,23 32:21 41:23 42:5 44:11 44:14 104:5 110:12 115:3 123:9 cases 22:14 23:15 23:20 27:8 74:3 cat 45:20 57:22,24 61:7 98:24 categories 61:10 61:17 62:4 category 27:15 121:1 catenacci's 95:15
	c c 2:1 97:9 129:2 ca125 57:12 ca929 57:13 cabraser 2:3 33:5 33:19 115:9 california 5:10 called 10:4 25:24 54:4 57:12,13 71:23 75:11 calls 29:10 30:2 68:16 89:7 96:7 camber 3:1 camden 1:2 camera 8:19 campus 38:18 cancer 12:24 17:6 17:7 18:22,23 19:8 22:7 25:5 26:21 27:2,3 44:24 45:3,11,12 45:18 51:1 53:5 55:24 56:1,10,13 56:15,20,20,22		

[caught - concerned]

Page 5

caught 72:21 causation 17:12 19:8 97:6 cause 74:12 97:3,5 102:18,22 112:8 129:7 caused 13:4,5 96:10 causes 102:1,6 causing 74:12 caution 14:21 31:5 41:8 cell 26:3 center 16:1,3 27:10 37:1 centers 27:12,13 central 1:10 centre 4:22 century 5:9 certain 21:12 33:17 42:9 52:15 60:20 66:3,16 74:11 75:9,12,23 76:2 77:5,11 81:12 86:21 88:15 91:8,14 95:24 107:8 108:8,13 109:15 certainly 45:8 certainty 62:23 63:10,13,14 80:1 80:14 certificate 6:14 certification 111:23 127:13,14 127:14 certified 1:14 129:3 certify 94:3,18,24 95:9 129:4,14,17	cetera 124:13 chairman 39:9 chance 72:22 104:13 change 119:6 122:22 132:4,7,10 132:13,16,19 changes 81:6,13 131:10 133:6 changing 55:4 charchalis 5:8 128:23 charge 64:17 117:14 118:17 charged 119:5 chattanooga 4:4 chemicals 18:21 chemistry 93:24 chemotherapeutic 75:9 chest 90:8 91:23 chicago 1:16 8:6 37:5,9,23 chugging 99:14 cincinnati 5:4 circumstances 69:6 cirrhosis 81:9 93:15 cite 47:20 claim 13:2,3 claiming 18:19 clarification 128:10 class 25:23 50:20 64:18 65:23 67:13 67:19,19,22 68:14 68:22 69:7 74:18 76:1,21 80:3 81:17 89:8,12,12 89:15 90:10 97:7	97:21 111:2 124:7 124:12 127:20 128:4 classes 67:16 classifications 19:23 classlawdc.com 2:11 cleaning 19:14,16 20:3 clear 18:10 46:12 83:16 clerkships 38:17 clia 111:23 127:13 127:14 client 15:14 31:14 clinic 27:23 clinical 38:16,17 38:22 39:7,7 45:13 72:4 clinically 85:21 close 27:20 105:6 closer 8:20 closets 21:13 coan 4:8 coldcuts 77:8 colleagues 29:7 college 2:15 cologuard 88:19 colon 49:8,11 53:5 73:22 88:19 91:18 colonic 45:17 colonoscopies 45:15 46:21 47:11 48:19,20 50:11 colonoscopy 45:24 47:1,5,7 48:10,24 49:7,12,14,17,19 52:19,20 53:13 71:5 73:21 80:22 88:22 89:4,15	91:11,18 97:12 colons 48:3,10 colorectal 92:4 come 29:4 46:14 49:18 55:4 99:5 100:10 109:19 comes 47:22 59:11 78:14 79:8 comfort 99:5 commencing 1:17 committee 2:13 common 47:10 commonly 20:3 communication 31:9 116:17 117:8 communications 31:6,12 community 39:1 109:3 comorbidities 46:23 49:15 52:10 53:19 71:2 89:16 126:13 comorbidity 71:10 companies 66:3 company 32:19 111:20 compensated 62:7 complete 30:19 46:13 133:8 completed 129:16 131:17 complication 47:8 compound 123:1 comprehensive 51:1 concern 108:22 concerned 49:4 108:9 109:19,20 120:20 121:8,8
---	---	--	---

[concerning - data]

Page 6

concerning 40:2,3 conclude 67:4 127:6 concluded 37:21 96:10 concludes 128:15 conclusion 15:12 30:3 68:17 89:8 condition 17:10 109:11 conditions 26:3,18 50:22 57:10 72:13 73:22 81:8 121:6 125:6 conduct 71:4 conducting 74:8 107:11 confirming 62:15 confusion 127:24 congress 87:24 connection 30:23 consequences 94:8 95:13,24 consider 48:23 63:6 65:8,10 67:10 84:15 89:20 109:5 considered 42:9 42:21 63:7 65:17 81:8 97:22 127:17 considering 98:1 consist 44:19 consistent 74:13 constructed 66:15 contact 33:19,21 34:4 115:18,22 contacted 32:19 34:3 115:4,14 containing 123:20 contains 103:22	contaminants 103:9 contaminated 66:4 80:4 81:18 128:2,7 contribute 74:12 cooperative 54:4 copies 131:14 copy 36:9 113:22 128:17,20 corporation 3:18 5:7 correct 19:2 21:23 21:24 22:1,2,12 23:16 24:6,7 25:9 25:17 26:7 29:12 29:13 30:1 33:20 34:9,17 35:10 37:11,12 38:11 40:8,19 43:7,8,12 43:13 44:5,12 46:1,2 48:24 49:19,20,24 50:3,4 50:12 53:18 54:16 54:17,19 55:16 56:2,16,17 58:9 60:23,24 64:8,9 66:17,18,20,21 67:8,9 68:12 74:10,15,16 78:5,6 78:11,12,13 79:9 79:10,14,17 80:6 80:16,17 81:19,23 82:14,15,18,19 83:10,11,12,18,19 83:23 86:1,2 88:16,17,21,23,24 89:10,17,23 90:15 91:4,5,9,19,20 95:7,24 97:7,8,14 101:7,14 102:6,14	102:15,18,24 103:15,16 104:5 104:11,12 106:16 107:10,13 108:7 114:22,24 116:9 116:10,18,19,22 116:23,24 117:5,6 117:9,10,12,23 118:1,3,4,8,9,16 118:18,19,21 119:4,6,20 121:4,5 121:8 128:4 129:11 133:8 correcting 117:9 corrections 133:6 correctly 9:1 74:23 80:10 94:16 120:21 cough 59:10 counsel 8:12 15:15 31:6,9,12,13,13 40:22,23 41:17 55:12 64:3 129:18 131:14 count 25:20 country 50:21 counts 26:2 county 129:2 couple 22:16 28:2 103:19 120:7,14 course 32:3 52:1,8 73:18 74:1 96:19 106:7 court 1:1,14 6:18 8:10,14 9:18 14:11,16 28:13 courtroom 14:17 62:10 cover 26:16 67:16 88:2	crafted 106:24 create 50:22 62:1 64:17 103:10 created 44:14 102:8 credentials 32:20 criteria 54:7 criticism 43:7 criticisms 101:21 cross 106:1 120:16 127:11 cs 131:15 csr 130:8 ct 90:8,10 91:22 culbertson 4:8 cumulative 74:19 74:21 75:1,7,10,12 75:15,21 76:8,15 76:17,22,23 78:2 78:10 79:12,13 83:9 85:20,24 current 24:8 36:11 currently 111:21 curriculum 7:4 34:1 36:9 cursor 26:1 custody 6:17 cutoff 15:4 cv 36:11,17 37:17 39:14 cvs 5:6 cystic 81:13
d			
d 5:2 d'lesli 3:20 d.c. 2:10 dallas 3:22 dangerous 43:3 daniel 2:20 data 47:19 72:16 72:18 86:22 87:9			

[data - diseases]

Page 7

87:13 98:12,23 99:2,2 103:8 date 8:4 132:24 133:12 dated 117:4 118:5 119:22 dates 20:21 davis 3:20 day 54:9,9 130:2 133:15 days 117:3 131:17 deadline 117:19 deal 25:2,5,7,10 26:14,19 124:4 dealing 124:6 dealt 20:11 26:6 39:17 death 17:21 54:13 december 118:6,6 118:7 119:9,22,23 decide 51:18,19 126:21 decided 126:12 deciding 52:4,13 89:21 decision 53:12 89:23 123:14 decisions 59:22 declare 133:4 declined 72:9 deemed 133:6 defendant 3:1,6,12 3:18 4:1,6 5:1,6 15:12,19 17:17 18:6 23:4,5,8,10 23:12 101:21 105:1 defendants 4:12 23:8 102:18,22 105:4 127:1,8	define 33:14 definition 89:8 97:20 98:8 degree 53:5 62:23 80:1,14 109:6,15 deleterious 109:16 demise 13:5 depend 123:3 depending 45:6 58:2 depends 58:6,8 59:17 72:4 124:20 deponent 131:13 133:3 deposed 12:4 17:9 17:12 18:16 21:20 deposing 131:13 deposition 1:7 7:3 8:5 10:18 14:10 14:12,13 16:9,14 17:3 18:2 21:17 22:15,16,24 28:15 29:10,12 36:17 62:10 104:14 119:13,16,17,19 128:15 129:14 depositions 12:3 18:14,16 20:19 21:19 24:5 describing 85:9 description 7:2 deserve 68:9 deserves 70:12 design 61:2 designed 55:23 56:5 57:10,17 60:19,21 61:16,18 desires 52:11 53:20 destined 94:6	detail 44:22 124:5 detailed 94:4 95:15 122:2 details 12:19 15:16 16:4 41:22 42:4,5,6 52:7 65:23 95:20 detect 57:18 81:7 86:21 87:13 88:3 88:15 91:8,14 92:21 93:8 detected 93:16 detecting 91:18 92:14 99:1 detection 81:5,6 86:18 determination 97:2,5 100:12 123:8 determine 54:3 71:20 85:20 93:7 124:12 determined 79:13 99:18 100:4,17 101:1,1,10 determining 52:15 90:5,5 develop 33:11 34:11 40:10,23 41:5,17 42:16 43:5 44:9 51:4 94:6 106:3 developed 44:16 45:3,12 72:20 110:15 developing 33:16 42:1,10 44:18,24 45:16 59:15,24 76:2 80:3,15,19 81:11,11	development 18:22 45:18 65:8 diagnosed 53:2 diagnosis 13:4 17:11 121:4 diagnostic 80:2,14 died 9:1 diet 74:20 76:16 76:23 77:3,17 78:4,15 79:9 82:21 123:19 dietary 74:22 125:4 difference 56:18 112:5,21 different 30:5 57:5 59:19,20,20 60:1 63:13 69:13 70:5 70:5,16,17,20 80:8 82:3,12 87:8 123:22 125:11 differently 56:11 difficult 124:22 direct 10:6 direction 51:17 disclose 31:6 discovered 122:3 discuss 91:21 discussed 34:24 64:5 71:9 103:22 104:1,10 125:12 discussing 32:21 78:22 118:12 discussion 9:14 32:9 disease 13:4 26:3 27:9 47:7 52:8 72:23 diseases 65:12 70:8
---	---	--	--

[disorders - exam]

Page 8

disorders 24:22 25:7,10,13,20 26:6 109:21 distinction 59:8 distinctions 58:19 59:4 district 1:1,2 diverticulitis 73:23 diverticulosis 73:24 dlesli.davis 3:23 dna 91:12 doctor 15:21,23,24 17:13 18:4,5,5 36:6,22 43:19 48:22 49:2,4 50:7 60:15 67:12 70:4 90:5 91:6 94:2 96:9 98:11 101:20 103:17 104:3 105:22 106:23 107:6 108:21 109:22 112:5 113:10 114:14 120:8 122:6 125:13,16 126:7 126:12,23 doctor's 70:13 126:15 doctors 15:24 89:19 121:24 document 90:12 documented 106:10 documents 22:19 29:14,17,18,21 doing 19:19 22:6 54:1,10 57:21 62:16 72:24 82:9 98:8 111:11,12	122:16 127:7 dosage 63:24 74:10 dose 61:7 90:8 98:24 double 30:11 dr 7:5,7 10:8 26:9 28:22 32:16 95:15 99:13 105:13 127:13 draft 40:10 55:10 drafts 31:3,16,18 draw 73:11 111:19 drive 1:15 7:6 8:6 103:21 dropped 14:15,18 15:8 drug 43:7 75:11 100:11 124:8 drugs 39:21 40:7 40:13,17 75:10,24 103:8 duane 4:15 105:3 duanemorris.com 4:17 ductal 81:7,13 due 94:6 118:20 duly 10:4 129:6 duration 64:1 74:10 dysplasias 25:22 dysplastic 25:21	east 3:3 5:9 eastern 54:4 ecog 54:4,6 edward 1:8 6:6 8:8 10:3 129:5 131:5 132:2,24 133:2,4,12 effect 43:10 efficiently 64:14 eight 22:22,23 23:2 eighty 96:24 either 18:11 20:24 22:18 48:4 109:1 126:7 129:18 elderly 47:6 49:7 72:20 electronic 128:20 128:24 elements 108:9 ellie 3:19 ellie.norris 3:23 employed 24:16 endogenous 82:21 endoscopy 81:5 88:23 89:4,16 english 76:7 ensure 64:14 entail 38:12,14 entire 30:20 entitled 1:13 enzymes 93:21 94:1 epidemiologic 112:10 equal 80:5 81:21 82:18 equipped 27:22 errata 131:11,13 131:17	erratas 131:15 errors 55:17 esophageal 86:22 88:15 91:9,14 92:4,11 esophagus 27:5 81:6 109:8 especially 53:23 65:22 established 42:6 42:20,23 55:3 64:13 66:2,7,8,9 estimate 22:17 90:22,24,24 estimated 91:1 et 8:8 124:13 131:4 132:1 133:1 evaluate 59:11 evaluated 56:12 74:2 79:12 111:15 evaluating 84:16 85:13,15 87:22 evaluation 42:13 53:14,22 57:8 59:9 78:18 81:9 81:12 123:13 124:11 evaluations 87:6 event 129:19 everybody 70:12 122:2 evidence 68:5 exact 48:6 118:11 128:4 exactly 12:21 17:7 47:16,18 54:22 58:13 90:6 103:7 115:21 exam 45:13,13 57:8 71:22 92:19 121:13,20
---	---	---	--

[examination - foregoing]

Page 9

examination 6:6 10:6 71:21 93:6 106:1 114:12 120:16 125:19 127:11 examinations 93:17 examined 10:5 example 45:8 47:3 57:11 59:9 60:3 71:5,14 80:22 98:23 109:8 examples 92:11,13 exams 45:13 110:9 excluded 68:14,22 exclusively 26:15 excuse 40:22 94:10 executive 2:13 exhibit 6:17 7:3,4 7:5,6,7 28:14,16 28:23 36:1,3,6,7 43:15,16,19 55:8 103:21,23 113:16 113:17 114:14,16 127:20 exhibits 6:4 7:1 36:15 exists 80:1 100:10 expectation 72:14 experience 38:16 39:1 42:15 44:22 47:23 51:21 expert 12:14,15,24 18:17 21:22 22:4 22:11,14,18 23:3 24:1 32:19 33:18 33:24 34:21 42:7 42:20 55:22 expert's 35:3	expertise 63:11 experts 34:24 35:8 35:9 42:23 43:10 50:20 64:6,8 65:6 66:20 67:3,8 68:11 74:9 78:17 79:6,7 83:17 91:1 91:4 103:14 explain 45:7 52:18 66:22,24 explore 69:16 exposed 18:21 19:7 33:13,17 34:12 42:9,12 72:19 73:1 77:2,5 82:8 123:15 exposure 18:19 67:6 68:7,8 70:10 70:10 75:1,2,7,9,9 75:11,13,23,24 76:17 78:2,10 79:1,3,12,13 80:4 80:5,10 81:18,21 82:5,13,17 83:1,15 83:22 84:11 85:8 90:4,16,20,22,23 99:19 100:4,19 101:11 110:18,22 124:13 126:10 exposure's 60:3 exposures 58:21 74:21 76:24 94:7 95:11 110:5 express 4:1 extent 16:18,23 30:2 34:14 68:16 94:9 extra 110:4 120:1	f faced 80:3 facilities 27:10 facility 27:24 fact 17:4,19 98:13 102:10 factor 53:9,12 78:15 factors 54:2 factory 19:15 facts 41:9 104:10 faculty 37:22 39:12 fails 131:19 fair 48:8 53:4 116:2 fairly 20:2 familiar 33:5 75:14 77:19 families 45:2 family 52:12,14,17 53:1 61:20,21 109:2 126:8 fatty 81:10 93:16 fault 17:12 favor 15:11 fda 100:11 111:21 111:22,24 112:2,3 112:4 fecal 91:12 feel 104:13 feeling 105:20 fellows 38:24 fellowship 37:8,13 37:19,20 felt 41:23 92:20 fhs 4:23 figure 47:20,22 file 30:20 34:2 files 103:22	final 118:5 find 14:2,4 19:7,10 20:20 81:12,12 122:11 finding 121:22 findings 109:8 finish 14:22 50:6 firm 2:15 13:22 33:1,3,4 105:1 firms 33:6 first 10:4 12:4 22:9 23:24 28:14 29:1 32:16 34:3 53:4 55:21 58:16 66:16 71:17 76:12 81:22 89:3 92:10 103:19 115:6,7,14 115:17,21 129:6 fit 54:3 72:5 73:3 five 38:4 60:6 71:5 88:22,23 89:5,16 97:12 99:11 114:7 117:3 floor 2:4 4:9,22 florida 2:22 focus 70:8 121:14 folks 36:18 43:18 113:20 follow 45:2,10,12 45:17 51:10,13 61:4,6 90:5 109:12,23 120:15 followed 27:13 109:18 following 67:2 follows 10:5 food 77:5,7 foods 77:8 123:19 foregoing 129:11 129:15 133:5
--	---	--	---

[form - guess]

Page 10

form 91:7	93:14 111:8,9,21	127:10,12 128:9	110:11 111:8
formally 127:6	111:22	131:1	114:3,4 122:3
forming 63:21	galleri's 87:10	gene 45:1 53:3	goes 10:23 59:8
formulate 106:18	92:15	general 26:2 53:14	going 10:14 11:1,2
forth 127:21	gammopathy	57:7 58:12 60:2	11:17 20:19 21:15
found 15:11 78:18	25:24	73:14 109:3,5,6	28:13 31:5 43:14
78:21	gastroesophageal	121:23 126:8	49:11 50:18 53:23
four 10:22 16:14	17:6	generally 13:24	53:24 54:15 56:11
29:2 54:8,12,13	gastrointest 45:17	51:10,11	59:10 60:1 63:4,6
58:5 60:13 66:19	gastrointestinal	genetic 44:24 45:3	70:15 86:3 99:14
67:3 68:10 99:7	27:2,4 45:10	45:9 53:11 60:21	102:20 103:17,17
106:6 114:19	gauge 54:2	61:21 107:8,12,16	104:8,18,23
frame 116:16	gcoan 4:11	107:21 108:8	109:17 122:18
117:20	geman 2:3 6:12	109:9,11,11,13	gonna 70:13
frank 4:20 128:19	8:24 9:5,8 14:21	121:6	good 8:1 10:8,9
frequently 55:24	14:24 15:2,4	genetics 108:13	48:22 49:2 50:7
57:22,24 58:1	16:18,21 20:16	geoffrey 4:8	72:5 73:24 92:13
fresh 77:10	21:2 28:20 30:2	geoppinger 5:2	92:15 105:13
friend 14:3	30:14 31:1,5	6:10 120:7,9,12,13	120:8,12 121:20
front 33:8 114:19	34:14 41:8,12,20	120:17 123:6,11	121:21
124:21	46:7,10,16 48:15	124:14 125:1,13	gordon 4:19
fruit 77:10	53:7 56:7 58:22	georgia 3:16 4:3	gosh 116:5
fulbright 3:20	63:1 67:24 68:16	getting 45:15	graduate 36:24
full 38:4 39:12	69:1,9,18 70:18	58:15 62:12	graduated 37:2
fully 28:8	71:7 73:9 78:7	121:22	grant 4:21
function 94:1	81:24 83:24 84:6	gi 27:3 89:4	great 8:22 36:20
functional 52:10	84:8,12,20 85:10	give 12:19 40:24	88:4
54:10	86:3,8,24 87:11	41:18 47:3 104:23	greater 81:21
fund 64:13	88:11 89:6 92:6	125:2	82:18
funded 64:20	94:9,11,14,22	given 24:4 29:5	greenberg 3:9,14
funding 64:15	95:14 96:1,7,15	66:10,12,13 72:22	10:13
further 66:14	99:21 100:7,20	127:15 129:8,12	gross 24:9
91:21 125:14	101:12 103:3,5	133:9	group 15:24 41:24
129:14,17	104:15,24 105:2	giving 71:13	42:1 54:5 56:10
g	105:11 106:19	glad 49:2	62:2 110:16
gallbladder 27:6	107:22 110:13,23	glenn 3:8 10:10	gtlaw.com 3:11,11
galleri 86:16,16,17	113:3,19,22	go 8:21 9:6,10,11	3:17
86:20,23 87:9,13	115:11,19 116:4,7	11:18 21:14 22:16	guaranteeing
87:20 88:9,14	122:24 123:10	32:6 36:22,23	94:21
91:8,13,13 92:10	124:1,18 125:7,22	41:7 55:21 63:20	guess 102:8
92:15,16 93:8,13	126:16,24 127:6	79:20 98:17 105:6	117:13

[guessing - individual]

Page 11

guessing 48:4 guidance 40:24 41:19 guide 54:14 90:4 guideline 90:3,6 126:11,19 guidelines 50:15 51:10,12 54:21,23 61:4,6 65:16,17,20 65:21 87:16 88:7 89:18 97:17 109:23 126:20 gynecologist 45:19	heimann 2:3 held 1:15 8:6 heller 5:14 help 51:17 54:14 90:4 92:21 93:18 hematology 24:19 24:20,21 25:4 26:16 37:8,16 38:1 hemophilia 26:3 hepatic 93:16 hepatocellular 81:11 hereto 133:7 hereunto 130:1 high 42:1 44:23 45:15 55:24 57:5 57:23 58:8,11,18 59:24 61:22 97:13 97:15,17 higher 67:6 hinshaw 4:8 hinshawlaw.com 4:11 histories 61:21 history 42:7 45:14 46:23 52:12,14,17 53:1 57:8,14 62:3 70:11,13 71:2,20 89:17 92:19 93:4 93:17 121:22 125:3,4,10 126:13 hold 80:13 104:4,7 hollis 2:15 hollislawfirm.com 2:17 home 20:4,24 honestly 14:20 hospital 16:1,2 24:11 39:13	hour 60:7 62:10 62:11,12 116:21 117:13 118:3 119:19,22 120:1 hourly 62:8,8,9 hours 106:8,11,21 116:15 117:11 118:14 119:2,11 119:14,22 house 21:13 hp 105:4 huahai 4:12 hudson 2:4 hum 23:23 human 110:1,19 112:6,6,7,9,11,15 112:22 113:1,2 humans 99:20 100:6,18 112:8 husch 4:3 huschblackwell.... 4:5 hypothetical 84:13 113:4 122:19 123:1,17 124:2 125:8 126:17	identify 66:16 78:14 illinois 1:15,16 8:6 24:9 37:2 129:1 illnesses 25:23 impact 127:17 important 79:4 improve 94:5,20 inaudible 128:23 include 27:1 45:13 57:21 71:20,21,22 71:23 84:23 85:3 87:5 90:8 93:23 106:12 123:19 included 93:4 includes 24:15 44:23 92:18 93:24 106:12 121:13 including 96:3 119:16,17 123:14 incomplete 84:12 113:3 122:24 124:2 125:7 126:16 increase 33:16 70:10 74:11 112:14 increased 42:21 68:7 74:22 80:10 82:16 independent 13:23 42:22 43:3 123:14 independently 79:12 102:13,15 102:21,23 index 6:1,4 7:1 indigenous 77:19 78:1,5,15,19 79:9 individual 51:14 59:22 69:12,17 70:14 71:3 89:24
h	hereto 133:7 hereunto 130:1 high 42:1 44:23 45:15 55:24 57:5 57:23 58:8,11,18 59:24 61:22 97:13 97:15,17 higher 67:6 hinshaw 4:8 hinshawlaw.com 4:11 histories 61:21 history 42:7 45:14 46:23 52:12,14,17 53:1 57:8,14 62:3 70:11,13 71:2,20 89:17 92:19 93:4 93:17 121:22 125:3,4,10 126:13 hold 80:13 104:4,7 hollis 2:15 hollislawfirm.com 2:17 home 20:4,24 honestly 14:20 hospital 16:1,2 24:11 39:13	hum 23:23 human 110:1,19 112:6,6,7,9,11,15 112:22 113:1,2 humans 99:20 100:6,18 112:8 husch 4:3 huschblackwell.... 4:5 hypothetical 84:13 113:4 122:19 123:1,17 124:2 125:8 126:17	identify 66:16 78:14 illinois 1:15,16 8:6 24:9 37:2 129:1 illnesses 25:23 impact 127:17 important 79:4 improve 94:5,20 inaudible 128:23 include 27:1 45:13 57:21 71:20,21,22 71:23 84:23 85:3 87:5 90:8 93:23 106:12 123:19 included 93:4 includes 24:15 44:23 92:18 93:24 106:12 121:13 including 96:3 119:16,17 123:14 incomplete 84:12 113:3 122:24 124:2 125:7 126:16 increase 33:16 70:10 74:11 112:14 increased 42:21 68:7 74:22 80:10 82:16 independent 13:23 42:22 43:3 123:14 independently 79:12 102:13,15 102:21,23 index 6:1,4 7:1 indigenous 77:19 78:1,5,15,19 79:9 individual 51:14 59:22 69:12,17 70:14 71:3 89:24
h	hereto 133:7 hereunto 130:1 high 42:1 44:23 45:15 55:24 57:5 57:23 58:8,11,18 59:24 61:22 97:13 97:15,17 higher 67:6 hinshaw 4:8 hinshawlaw.com 4:11 histories 61:21 history 42:7 45:14 46:23 52:12,14,17 53:1 57:8,14 62:3 70:11,13 71:2,20 89:17 92:19 93:4 93:17 121:22 125:3,4,10 126:13 hold 80:13 104:4,7 hollis 2:15 hollislawfirm.com 2:17 home 20:4,24 honestly 14:20 hospital 16:1,2 24:11 39:13	hum 23:23 human 110:1,19 112:6,6,7,9,11,15 112:22 113:1,2 humans 99:20 100:6,18 112:8 husch 4:3 huschblackwell.... 4:5 hypothetical 84:13 113:4 122:19 123:1,17 124:2 125:8 126:17	identify 66:16 78:14 illinois 1:15,16 8:6 24:9 37:2 129:1 illnesses 25:23 impact 127:17 important 79:4 improve 94:5,20 inaudible 128:23 include 27:1 45:13 57:21 71:20,21,22 71:23 84:23 85:3 87:5 90:8 93:23 106:12 123:19 included 93:4 includes 24:15 44:23 92:18 93:24 106:12 121:13 including 96:3 119:16,17 123:14 incomplete 84:12 113:3 122:24 124:2 125:7 126:16 increase 33:16 70:10 74:11 112:14 increased 42:21 68:7 74:22 80:10 82:16 independent 13:23 42:22 43:3 123:14 independently 79:12 102:13,15 102:21,23 index 6:1,4 7:1 indigenous 77:19 78:1,5,15,19 79:9 individual 51:14 59:22 69:12,17 70:14 71:3 89:24

[individual - language]

Page 12

<p>90:6 121:17 123:8 124:8 126:20,21 individually 74:2 individuals 73:17 infection 73:12 inflation 119:24 information 32:20 33:21 34:1,22,23 64:2,4,5 122:20 ingested 74:19 76:21 initial 123:13 initially 115:5 inpatient 27:19 input 55:12 insist 88:1 insitu 81:7 instance 71:13 institute 32:19 33:18 instruction 41:1 41:18 intake 125:4 128:7 intend 111:10,12 intense 62:1 interaction 15:13 interested 32:21 33:23,24 129:19 internal 37:10 108:24 109:4 internist 109:5,6 121:14 internship 37:4,6 interrupt 45:21 intervention 64:15 introduce 32:24 introduced 32:22 investigated 100:9 investigational 51:22</p>	<p>invited 39:16 40:1 invoice 116:3,13 116:23 117:3,21 118:2,5,15 119:21 invoices 7:7 113:21 114:17,18 115:23 119:8 involved 19:14 24:23 32:23 44:17 51:22 87:23 115:3 irbesartan 1:4 isidro 3:8 10:13 36:19 104:20 114:3 127:5 128:24 isidron 3:11 issue 79:4 107:12 issues 15:15 17:10 25:19 107:8,16,21 108:9</p> <p>j</p> <p>j 2:3 131:1 james 4:2 james.spung 4:5 january 1:9,16 8:4 130:2 131:3 jason 4:21 jeff 5:2 120:9,13 jersey 1:2 jgeoppinger 5:5 joined 37:22 judgment 50:1 126:15 jump 86:3 justify 103:10</p> <p>k</p> <p>k 129:2 kansas 2:16 kaplan 1:8 6:6 7:5 8:9 10:3,8 28:22</p>	<p>32:16 48:2 99:13 105:13 127:13 129:5 131:5 132:2 132:24 133:2,4,12 kaplan's 7:7 karnofsky 54:6 kate 3:14 keep 99:14 kelly 1:14 8:10 129:3 130:7 kerner 3:8 6:7,9 8:18,22 9:3,7,9,11 10:7,10 15:1,3,7 16:20 17:14 20:22 21:6 28:18,21 30:5,7,15 31:7,10 32:3,5,13 34:16 36:1,5,15,20,21 41:7,10,11,13,15 41:16 42:3 46:14 46:17 48:16 53:15 56:14 59:2 60:6 60:14 63:8 64:23 65:3 68:3,20 69:5 69:22 70:3,22 71:12 73:16 78:8 81:1,16 82:2 84:2 84:7,9,17 85:4,14 86:9,12 87:15 88:4,6,12,13 89:9 92:23 94:10,13,15 95:1,17,21 96:8,18 98:4,10 99:4,12 100:1,14 101:5,13 101:16,18,19 103:4,12 104:18 105:10 113:12,20 114:2,4,13 115:16 116:1,5,8 120:3,5 125:15 127:8 128:12</p>	<p>kernerg 3:11 kidney 94:1 kind 12:7 18:23 22:8 25:10,22 26:19 42:13 85:7 100:5,17 kit 111:19,20 kleinman 26:9,10 26:10 knew 20:18 21:15 50:17 know 10:23 13:17 14:18 15:9 16:2 16:11 19:16 21:19 29:23 31:11 41:13 47:16,18,22 48:1,6 48:9,12,13 64:21 66:8,8 75:16,18 77:13,18 82:20,22 83:8 87:19,21 88:7 100:9,11,13 101:3 104:1,9 109:2 112:5,11,17 118:11 121:17 knowledge 64:19 76:7 95:4 known 33:13,14 34:12 91:13 109:15,16 110:1 110:19 112:6,7,20 112:22 113:2</p> <p>l</p> <p>laboratories 4:18 laboratory 57:9 92:18 93:6,17,19 93:23 112:23 121:21 labs 94:1 language 63:2 76:7</p>
---	--	--	---

[laptops - man]

Page 13

laptops 8:19 large 27:6 111:4 late 13:4 law 2:15 33:1,3,4 33:6 lawyers 34:4 114:17 118:13 lay 63:12 laying 21:11 layman's 14:19 lchb.com 2:6 131:2 lct 81:21 82:18,20 83:1,21 84:10 85:9,16 89:2 learned 81:22 89:3 111:14,15 lectures 39:16 40:1 led 67:3 103:9 left 39:11 legal 8:3,11 30:3 32:22 42:13 44:11 68:17 89:8 131:23 leukemia 26:22 27:8,17,19 leukemias 25:13 level 75:23 77:14 77:16 80:4 85:2 124:13 levels 33:17 42:11 63:24 68:8 74:10 78:21 79:2 83:14 85:1,17 124:6 levin 2:20 lewis 3:3 lewisbrisois.co... 3:5 liability 1:4 license 130:8	lieff 2:3 33:5,19 115:9 life 17:9 75:12 lifetime 22:20 74:21 75:1,7,11,14 75:21 76:8,17,23 78:2,10 79:11,13 83:9 85:20,23 likelihood 97:22 likewise 14:24 limit 71:17 117:18 limited 40:19 limits 73:14 line 132:4,7,10,13 132:16,19 link 19:8 82:17 linked 19:11 53:1 liquid 86:19 list 71:14 listed 92:13 93:3 125:6 listing 92:11 literally 8:24 9:1 55:15 literature 19:17 48:6 51:21 65:13 99:17 100:3,10,16 100:23 101:2,9,15 106:13 116:17 117:8 litigation 1:4 10:12,16,17 21:21 21:22 22:3 23:19 32:17 40:11,12,15 42:8 79:19 89:3 107:1 120:14 little 34:9 56:1,11 56:22 60:7 66:14 87:7 91:21 105:15 108:4 122:1,1	liver 27:7 81:9,10 93:11,12,15,16,20 93:21,24 llc 4:13 llp 2:9 3:9,14,20 4:3,8,15,20 5:2 logistically 64:21 long 22:10 34:2,4 106:3,17 longer 122:1 longevity 72:14 look 8:23 18:8 20:13 52:2 55:6 63:2 69:13,16 70:5,6,14,15 81:9 92:18 103:24 105:18 looked 19:12 21:12 looking 21:14 28:18 31:16,18 39:14 41:3 62:18 91:10 103:8 108:21 looks 116:14 119:1 los 5:10 losartan 1:3 8:8 131:4 132:1 133:1 lot 14:4 19:13,15 19:16,17 55:3 104:2 105:21 120:24 122:20 lotman 4:14 6:8,11 104:22,22 105:3,3 105:12,17,20 106:2,22 108:1 110:17 111:6 113:8 120:18 125:16,17,20 126:2,23 128:21 128:21	low 25:19 26:2 61:7 90:8 98:24 lower 78:20 loyola 37:1 ltc 80:5 lung 27:2 57:22 90:23 91:2,23 92:4 98:24 lymphomas 25:13 27:3 lynch 45:1,8,22 46:4,5,18,20 47:4 49:14,22 50:10 52:21,22,24 60:22 109:9
m			
m 4:8 m.d. 1:8 6:6 8:9 10:3 129:5 mail 33:22 main 97:19 maintained 38:6 39:12 majority 26:24 27:12 78:19 making 97:4 male 72:7 males 71:17 malignancies 27:2 33:16 42:10 45:4 45:10 59:24 94:6 malignancy 50:20 malignant 25:12 81:6,8 97:18 malpractice 12:8 12:9,10 13:24 22:14 23:14,19 24:2 mammogram 81:7 man 72:16 73:4			

[manner - move]

Page 14

manner 100:12 manufactured 43:2 66:2 manufacturers 63:23 66:3 mark 28:14 36:1 43:14 103:21,23 113:16 114:14 marked 28:16,23 36:3,6 43:16 55:8 113:17 127:20 marker 57:12,13 marlon 26:9,9 marrow 25:20 27:21 massachusetts 4:10 materials 42:8 matter 1:13 8:7 62:8 maywood 37:2 mcharchalis 5:10 mckesson 3:18 md 131:5 132:2,24 133:2,4,12 mdl 1:3 mean 11:15 14:19 38:21 44:20 48:13 48:17 53:21 55:15 57:8 58:1,2 59:17 62:24 63:9 69:20 75:17,18 80:18 82:14 94:18,24 98:23 101:6 112:8 114:1 124:11 meaning 80:5 means 57:3 75:16 75:18,22 82:6 95:3 meant 15:9	measure 52:9 media 9:17 32:8 32:12 60:9,13 99:7,11 114:7,11 128:14 medical 12:9,10 14:5 16:1,3 19:4,5 23:19 24:2 36:23 37:1 38:1 42:14 44:10,11,15,16 50:1 63:11,14 64:12,17 67:13 71:2 72:13 74:18 75:5 76:9 79:21 80:1,14 82:7 95:3 99:17,20 100:2,5 100:16,17,23 101:9,10 106:4,24 107:3 109:7 113:1 126:13 128:5 medically 64:21 65:4,7 medicare 88:1,1 medication 28:4 medicine 37:10 38:7,10 109:1,4 meet 50:21 meetings 8:7 115:15 member 67:13,22 76:21 89:12,12,15 90:10 109:1 members 67:19,19 68:14,22 69:7 74:18 97:7,21 128:4 memory 28:5 mention 55:22 66:15 73:23 77:23 86:20 91:12,13	mentioned 22:13 26:18 27:3 52:22 53:19,19,20 60:19 61:15 70:7 72:12 88:14 93:14 109:9 120:19 merit 67:2 merited 67:4 met 10:10 metastatic 72:23 methods 54:4 mgus 26:1 midway 94:3 migliaccio 2:8,9 114:21 115:17 mild 25:21,21 mind 58:13 mine 14:3 ministerial 103:19 minute 60:6 99:5 104:23 minutes 10:11 49:5 misdiagnosed 13:4 misspoke 40:22 misstate 42:19 misstates 16:19,23 21:2 34:15 81:24 83:24 84:20 89:6 89:7,7 92:6 95:14 110:23 115:11 misunderstandin... 11:20 mittell 2:20 5:8 128:24 mitigate 80:2,15 moderately 97:13 97:15,17 modified 83:21 modify 82:23	modifying 84:18 84:19,22 moment 44:8,9 monday 29:17 30:1 103:23 monitor 45:4 55:24 60:5 85:22 monitored 56:11 65:24 68:9 109:15 121:13 monitoring 27:20 33:12 34:11 40:24 41:18,24 42:14,14 42:17 43:5 44:10 44:11,15,17,18,19 44:20 50:24 58:12 64:13,18 66:15 67:2,4,13 74:18 79:21 82:7 85:1 85:12 94:4,19 95:12 99:20 100:5 100:17,24 101:4 101:10 102:8 106:4,24 107:4,12 108:14 113:1 124:11 127:22 128:1,6 monoclonal 25:24 month 106:5 months 34:8 58:5 58:5,5 morbidity 98:9 99:1 morning 8:1 10:8 10:9,15 morris 4:15 105:3 mortality 97:23 98:9 99:1 move 8:19 62:6 86:13 88:4 103:17
--	---	---	---

[multiple - office]

Page 15

multiple 25:22 26:1 109:10 mutation 109:16 109:16 mutations 61:23 61:24 108:9 myeloma 25:22 26:2 mylan 4:18,18	82:21 85:24 90:20 96:10 99:19 100:4 100:19 101:6,7,10 101:11,24 102:6 102:14 123:19 125:4,5 ne 2:9 3:15 near 54:13 necessarily 49:12 53:11,12 57:15 58:10 125:11 necessary 69:11 133:6 necessitate 58:15 necessitates 99:19 100:5 need 9:7,8,9 11:10 20:13 31:4,15 53:10 63:1 69:7 99:4 121:20,20,21 124:10 needed 19:20 needle 73:12 96:4 needs 56:12 negative 30:11 94:8 95:13,23 neoplasms 25:21 network 51:2 never 96:12 101:15 new 1:2 2:5,5 3:10 3:10 10:10 55:4 nicholas 2:8 114:20 nigh 2:20 nilda 3:8 10:13 nine 67:4,5,14,16 67:16,20,23 68:15 68:23 69:8 nitrates 77:9	nitrosamine 35:1 77:4 85:24 nitrosamines 77:5 83:2 85:18 90:20 110:22 nmigliaccio 2:11 nod 11:8 non 25:16 128:4 nonresponsive 88:5 normal 54:9,11 82:9 norris 3:19 north 13:11 northshore 39:9 39:10,13 northwestern 13:11 37:5,9,14 norton 3:20 nortonrosefulbri... 3:23,23 notary 133:13,19 note 94:11 119:21 131:10 noted 8:12 133:7 notes 1:12 50:6 notice 1:18 7:3 28:15 29:11 36:17 november 114:1,1 116:13,15 117:4,5 117:5,22 119:23 number 7:2 22:19 30:19 38:18 50:14 54:2 60:4 71:14 97:1 110:7 numbers 108:20 111:4 nurses 24:16	o o 129:2,2 oath 10:24 object 46:10 94:9 objection 16:18,23 20:16 21:2 30:2 30:14 31:1 34:14 41:20 48:15 53:7 56:7 58:22 67:24 68:16 69:1,9,18 70:18 71:7 73:9 78:7 81:24 83:24 84:12,20 85:10 86:8,24 88:11 89:6 92:6 94:22 95:14 96:1,7,15 99:21 100:7,20 101:12 104:15 106:19 107:22 110:13,23 113:3 115:11,19 122:24 123:10 124:1,18 125:7,22 126:16 objections 30:4 obviously 11:1 60:16 occasionally 45:20 occasions 21:16 23:10 occurring 77:9 78:19 october 34:6,7 113:23 114:1 116:2,5,15 offered 71:11 offering 101:20,24 102:5,8,9,17 offhand 20:12 office 17:24 20:24 21:19 24:11,12 27:23 38:16 82:10
---	--	---	---

[office - patient's]

Page 16

112:2 oftentimes 27:19 oh 14:23 27:3 113:24 116:5 ohio 5:4 okay 10:23 11:12 11:16,20,21 12:2 13:16,18 15:17 16:5,8,13 17:22 18:10 20:23 21:16 23:2 26:14,19 30:5 31:19 32:16 37:20 39:14 40:22 41:13 42:18 43:6 43:14,19 44:8 53:16 55:6,7,10,21 57:19 58:16 59:3 60:6,15 61:15 62:6,21 64:12 66:11,14 70:4 71:13,18 73:6 74:3 76:8 82:11 88:19 89:22 90:14 91:17 92:1 94:2 94:18 97:1 98:16 99:4 100:15 104:10,18 105:14 106:7,12 107:14 108:3,19 109:22 110:4 112:11,24 113:8 114:2,14,20 115:4,9 116:2,20 118:14 119:1,3,7 119:18 120:3,4 121:10 122:9,14 122:18 123:17 127:19 128:9,11 old 20:21,24 21:8 71:24 72:3,16 73:4	once 90:10 oncologist 14:5 26:11,13 108:22 109:7 126:7 oncology 24:18,19 25:4 37:8,16 38:1 39:1,7,9 53:23 54:5 108:24 one's 74:11 ones 33:7 45:11 115:7 opine 14:6 18:20 102:2 103:8 opined 91:4 opining 17:11 48:5 97:6 101:23 102:24 103:1 opinion 67:12,18 68:4,5 79:21,24 80:13 82:23 83:20 84:19,19,22 89:6 90:19,19 95:6 101:24 102:5,9,17 opinions 10:16 62:22 63:5,21 74:15 101:21 104:4,7,11,14 106:18 opportunity 96:12 order 74:17 92:21 103:10 109:6 111:16,18 ordered 111:13 ordering 45:19 oregon 13:12 organization 50:19 87:17,19 88:8 outcomes 94:5,20 outline 65:22	outlined 65:13,15 67:15 68:15,24 69:21 97:16 110:9 126:6 outlines 65:23 outlining 90:3 outpatient 27:23 27:23 outside 40:12 outweigh 74:4 ovarian 57:11 overall 119:1 overland 2:16 oxford 4:22	94:2,3 paraphrasing 94:14 park 2:16 5:9 part 39:11 42:12 53:14,22 54:21 71:22 78:1,9 87:5 87:16 particular 16:6 65:23 80:9 82:5 82:13 90:1 127:16 parties 18:11 20:7 partner 10:13 26:22 party 12:11 17:15 18:11 129:18 pass 104:18 127:7 passed 22:8 patents 39:15 patient 17:3,8 18:9 18:17,18 42:15,15 42:15,16 44:18 47:4,6 48:23 49:7 49:14 51:24 52:1 52:3,5,9 53:2,4,10 53:14,21,22 54:1 54:15 55:23 56:19 57:14 58:6,9 59:5 59:18,22 61:13 69:12,14,15 71:3,4 71:9 72:5,9 84:10 87:4 89:1,1 90:4 97:15 121:18 122:15,22 123:4 123:12,14,18,22 124:10,16,21,22 124:23 125:3 126:9,22 127:18 patient's 52:7,11 53:10,20 59:23 70:14 96:10
---	--	--	---

[patients - predict]

Page 17

patients 26:17 27:11 33:12 34:12 41:24 42:9,10 43:1 44:21,23 45:2,2,10 46:3,6 46:19,22 48:10,18 48:19,23 49:5,21 50:2 51:7,15,18,20 53:23 55:5,24 56:5,9 57:5,6,7,9 58:7,10,14,18,20 58:20 59:4 60:20 60:21 61:3,4,10,11 61:16,17,20 62:1,2 64:18 65:9,23 68:7 69:12,17 70:5,16,20 72:7,18 72:20,24 85:5,7,8 87:23 89:19 93:5 94:6 96:20,22,23 97:2,13,17 100:24 107:7,14,15,18,20 108:5,8,13,16,23 109:4,7,12,18,21 109:22 110:5,12 110:16,18,22 111:3,7,17 120:19 120:23 121:10,17 122:10,19 123:15 123:23 124:5,12 124:16 126:3 pelta 5:14 pen 8:24 9:7,8 pending 17:23 pennsylvania 3:4 4:16,23 pensacola 2:22 people 33:23 63:22 64:14 78:19 80:3 81:17,20 82:8 109:3,10,19	127:3,21 128:2 percent 23:6 47:15 47:15,17 48:3,5,5 54:11 96:24 117:14,24 118:17 percentage 48:9 78:14 79:8 perforated 48:3 48:10 49:8 perforation 47:8 49:11 71:6 73:20 perforations 47:10 48:21 performance 52:8 53:20 54:5,6 55:1 72:5 performed 86:19 performing 54:9 72:15 periodic 97:10 person 2:3 3:8,8 13:23 18:18,23 56:12 71:24 74:1 82:9 90:2 124:8 person's 85:18 peruses 90:12 pharmaceutical 4:12,13 pharmaceuticals 3:1,7,13 4:7,18 10:12 pharmacy 5:6 philadelphia 4:16 phone 108:20 phrase 63:16 physical 45:13 57:8 71:21,23 93:6 physician 17:20 23:11,12 24:16,16 38:2 50:2 87:4	89:24 physicians 23:8 picture 22:9 105:16 piedmont 3:15 pietragallo 4:19 pietragallo.com 4:23 pill 77:17 78:4,15 pills 63:24 74:20 76:16,22 pittsburgh 4:23 place 126:15 129:15 places 13:13 20:21 61:9 plaintiff 2:19 13:1 19:1,2 23:18 44:2 91:1 plaintiffs 2:2,7,13 22:1 23:18 31:13 34:4,20 40:9,21,21 40:23 41:17 43:9 55:12 65:6 66:20 68:11 74:9 79:7 83:17 91:4 103:14 plan 106:4,4,24 110:11 124:9 126:14,19 planet 89:2 plasma 25:22 platelet 25:19 please 8:14 9:18 11:15 13:16 14:22 21:5 34:17 64:24 66:23 69:23 76:19 79:20 81:1 84:3 86:9 91:10 98:4 99:23 102:19 127:19 128:20	plus 100:11 point 24:9 43:6 82:7,24 92:16 98:9 99:17 100:2 128:5 polyp 97:18,18,19 polyposis 45:16 polyps 109:10 population 73:15 127:21 portion 65:1 70:1 81:2 84:4 86:6,10 98:5,20 pose 94:7 95:12,13 possession 30:17 possibility 109:17 possible 49:9 82:20 83:7,8 possibly 10:15 potential 68:13,21 69:7 94:5,19 125:4 practice 24:13,15 24:18,23 25:2,5 26:12,14,20 38:5 38:23 44:23 47:24 59:3 60:18 61:19 75:5 76:9 96:9 107:7 108:5 121:24 practices 121:23 practitioner 126:8 126:8,21 pre 26:1 81:6,8 97:18 precautionary 19:19 precursor 81:10 precursors 81:13 predict 81:15
---	---	--	---

[predispose - quick]

Page 18

<p>predispose 81:10 121:7</p> <p>predisposes 45:9</p> <p>predisposition 60:22</p> <p>preliminary 28:2 31:3</p> <p>prepared 74:13 77:8</p> <p>preparing 35:18 35:20 119:13</p> <p>prescribed 80:9 82:4,13</p> <p>prescription 111:19</p> <p>presence 129:10</p> <p>present 5:14 41:23 77:22</p> <p>presentations 39:17 40:1</p> <p>presented 40:11 40:16</p> <p>preservative 77:9</p> <p>pretty 19:19 26:21 51:8 54:7</p> <p>prevent 80:19 81:15</p> <p>previous 46:11</p> <p>primarily 24:23</p> <p>primary 121:24 126:7</p> <p>princeton 4:12</p> <p>prior 12:3 21:9 28:23 44:14 71:6 79:19 107:21 117:21</p> <p>private 24:15 38:5 107:7</p> <p>probable 112:6,9 112:11,13,19,20 113:1</p>	<p>probably 17:4 18:7 48:19 54:11 63:15 76:14 106:11,11 112:14 119:13</p> <p>problem 58:14 70:14 71:10</p> <p>problems 25:19 26:2 49:15 58:12</p> <p>procedure 48:11 52:15 90:1</p> <p>procedures 27:22 57:21 60:5 73:7 95:24 110:8</p> <p>proceedings 1:13</p> <p>process 123:21</p> <p>proctor 2:21</p> <p>produced 103:22</p> <p>product 78:21</p> <p>production 79:9</p> <p>products 1:4 20:2 33:15 35:1 102:18 102:22 123:20 128:8</p> <p>profession 63:7</p> <p>professional 24:8 62:23 63:9,13</p> <p>professor 38:7,9</p> <p>profile 93:24</p> <p>program 33:12 34:12 40:24 41:5 41:18,24 42:17 43:5 44:10,15,17 62:2 64:13,18 65:19,22 67:15 69:21 80:5,6 82:3 82:8,12 83:23 84:11 87:3 92:18 97:22 103:11 110:15 111:2 127:22 128:1,3,4,5</p>	<p>programs 44:18 44:19,20 55:23 56:4 58:17 59:21 60:19,21 61:2,16 61:18</p> <p>progress 13:5 36:19</p> <p>progressed 14:17</p> <p>progressive 72:23</p> <p>progressively 54:13</p> <p>proliferative 25:21</p> <p>proposal 95:12</p> <p>proposals 94:4,19</p> <p>propose 71:15 83:22</p> <p>proposed 67:13,19 68:13,22 89:12,15 90:10 97:7,21</p> <p>proposing 73:7 98:12 100:18</p> <p>prostate 71:14,16 71:19,22 72:21</p> <p>protocol 61:8 66:16</p> <p>protocols 51:4 59:20 60:2</p> <p>proven 112:8,22 124:6</p> <p>provide 29:22 31:4,21 47:5 54:15 55:12 60:2</p> <p>provided 29:18,24 30:9,12,20,23 41:9 43:21 59:13 64:2 68:6 122:20 128:2</p> <p>providing 38:22 119:8</p> <p>psa 71:23 72:1,8 72:11,15,24 73:3</p>	<p>public 44:16 133:19</p> <p>publications 39:15 39:17</p> <p>published 107:3</p> <p>pursuant 1:17 29:11</p> <p>put 27:14 33:18 43:11 61:24 64:18 64:22 90:17</p> <p>puts 90:20</p> <p>putting 23:18 43:1 53:13</p> <tr> <td colspan="4" style="text-align: center;">q</td></tr> <tr> <td colspan="4"> <p>qualifications 55:22</p> <p>qualify 74:18</p> <p>quantitate 54:1</p> <p>question 11:14,17 14:22 15:6 22:10 26:5 32:4 34:19 41:14 46:11 48:7 52:18 58:24 61:12 61:13 63:22 68:19 69:4 75:20 80:24 84:2 86:4 87:7 88:7 94:24 98:3 98:17 100:15 101:8 103:3 123:5 125:17,24</p> <p>questioning 103:18</p> <p>questions 10:14 11:2,2 28:2 60:15 99:16 104:21 105:22 113:9,12 113:14 120:8,15 125:14 126:24 127:9,9</p> <p>quick 120:14</p> </td></tr>	q				<p>qualifications 55:22</p> <p>qualify 74:18</p> <p>quantitate 54:1</p> <p>question 11:14,17 14:22 15:6 22:10 26:5 32:4 34:19 41:14 46:11 48:7 52:18 58:24 61:12 61:13 63:22 68:19 69:4 75:20 80:24 84:2 86:4 87:7 88:7 94:24 98:3 98:17 100:15 101:8 103:3 123:5 125:17,24</p> <p>questioning 103:18</p> <p>questions 10:14 11:2,2 28:2 60:15 99:16 104:21 105:22 113:9,12 113:14 120:8,15 125:14 126:24 127:9,9</p> <p>quick 120:14</p>			
q											
<p>qualifications 55:22</p> <p>qualify 74:18</p> <p>quantitate 54:1</p> <p>question 11:14,17 14:22 15:6 22:10 26:5 32:4 34:19 41:14 46:11 48:7 52:18 58:24 61:12 61:13 63:22 68:19 69:4 75:20 80:24 84:2 86:4 87:7 88:7 94:24 98:3 98:17 100:15 101:8 103:3 123:5 125:17,24</p> <p>questioning 103:18</p> <p>questions 10:14 11:2,2 28:2 60:15 99:16 104:21 105:22 113:9,12 113:14 120:8,15 125:14 126:24 127:9,9</p> <p>quick 120:14</p>											

[quickly - report]

Page 19

quickly 11:23 86:5 113:15 114:15 quite 11:14 78:20 99:13	103:2 reask 108:2 reason 49:16 59:23 70:23 71:1 92:12 122:16 131:11 132:6,9,12 132:15,18,21 reasonable 62:23 63:7 80:1,13 reasonably 99:19 100:4 reasons 46:23 49:6 49:9,13 recall 19:12,13 21:18 63:19 115:8 115:21 receipt 131:18 receive 57:7 64:15 received 29:17 recommend 49:6 49:11,13,17 71:5 72:1,8,23 73:3 84:11 88:19,22 110:4,7,20 111:16 125:2,21 126:1 recommendation 50:2 61:7 87:2,8 90:9 recommendations 51:6,16 89:18,19 90:6 recommended 46:20 50:10 110:21 111:3 123:16 126:4,11 recommending 73:13 87:3,4 89:14 91:7 127:22 128:1,3 recommends 87:20	record 8:2,13 9:10 9:11,13,15,17 11:19 22:15 32:6 32:8,10,12 60:9,13 65:2 70:2 81:3 84:5 86:7,11 98:6 98:21 99:7,11 104:1 105:8 114:3 114:4,7,11 128:16 record's 46:12 recorded 11:3 records 18:9 19:4 19:6 20:21,24 21:8 62:9 118:7 118:10,11 recross 125:19 rectal 91:18 recurrence 56:1 56:16,20,22 57:6 57:18,24 58:19 redirect 114:12 reduce 98:9,24 reduced 97:22 129:9 reefer 4:21 refer 27:24 referenced 129:9 129:13 131:6 references 118:12 referred 68:11 referring 45:18 92:19 93:19 refuses 47:9 regard 22:6 regarded 51:8 regardless 89:16 89:17 regards 75:8 regular 71:22 regularly 50:22 61:11,14	related 18:22 24:22 49:16 71:10 109:1 relationship 31:14 relative 53:5 91:2 129:17 relied 67:8 relying 43:9 74:14 83:17 remember 12:21 13:14,16,19,22,24 14:1 15:10,16,17 15:19 16:4,5,10 17:7,22 18:1,4,11 19:21,23 20:5,7,12 20:18 24:5 29:8,9 34:2 42:19 44:6 50:18 115:14 118:13,24 remote 36:18 render 79:2 repeat 15:6 21:5 34:19 41:14 49:1 68:19 75:20 76:19 80:24,24 98:3 99:23 102:19 rephrase 84:7 107:17 report 7:5 10:16 35:6,7,9,18,20,23 36:13 40:9,16,19 43:21 55:6,10,13 58:17 60:18 62:19 62:20,22 64:22 65:15 70:7 74:13 74:15 76:13 77:23 78:11 81:22 82:23 89:7 91:6 92:2,24 93:19 94:11 95:15 95:16,19,20 97:9 106:4,15 116:17
---	--	---	---

[report - screening]

Page 20

117:8 118:12 125:6 126:6 reporter 1:14 6:18 8:10,14 9:18 28:14 101:17 128:17 129:4 reporter's 6:14 reports 64:6,8 65:5 66:9,12,13 67:3 76:11 100:10 102:12 117:9 represent 105:1,4 120:13 representing 8:3 10:11 request 29:14 30:19 34:20 requested 28:17 30:12 31:21 36:4 43:17 65:1 70:1 81:2 84:4 86:6,10 98:5,20 113:18 requests 29:19,21 29:24 30:8,9,13 31:23 33:22 require 27:21 70:16,20 required 133:13 requires 27:10,18 27:19 residency 37:3,4,4 37:7,10 residents 38:15,24 resources 35:21 35:22 respect 50:10 52:2 69:17 79:11 93:20 101:22 104:5 respond 34:13,20 responded 33:22	response 29:18 113:13 127:2 responses 30:3 responsibilities 38:12,14,18 result 14:14 101:11 retain 34:21 retained 13:20 21:22 22:4,18 23:3,4,7,11,17 24:1 retainer 116:3 return 131:13,17 reveals 125:3 review 14:5,7 18:20 19:3,5,5,6 21:8 22:15,19 29:15 33:11 34:22 34:23 35:4,14,18 42:13,16 43:4 44:11 51:14,15 65:5,13 66:19 79:6 103:23 116:17,18 117:8,9 118:7,10 131:7 reviewed 19:16 20:20 21:1 35:8 35:20 51:23 67:2 reviewers 42:7,20 reviewing 18:17 32:21 35:13 62:9 106:13 reviews 50:20 rgeman 2:6 131:2 right 15:2 16:16 28:23 29:11 31:7 33:2 36:2 48:8 51:8 52:23 76:18 87:7 96:6 99:5,14 99:16 107:9,12	108:6 112:3,19,21 114:23 117:15 123:24 124:9 risk 33:16 42:1,10 42:12,21 43:1 44:23 45:16 49:7 49:8,15 53:10 55:24 56:19 57:5 57:24 58:8,11,18 59:13,14,24 60:4 61:22 62:1 65:9 67:6 68:7 73:14 73:21 74:11 75:12 76:1 79:2 80:10 80:15 82:16 90:17 90:21,22 91:2 97:13,15,17 100:13,24,24 101:1 109:16,20 112:15,15 120:20 126:10 128:7 risks 35:1 49:18 49:22 59:20,20 65:24 70:11 73:6 73:8,11,17 74:3,22 80:2 94:7 95:13 95:23 96:5 rite 5:7 road 3:3,15 24:9 role 37:24 38:3,6 39:11,12 79:15 roles 38:17 room 9:5 96:4 rose 3:20 ross 3:21 rotate 38:15,20 rotation 38:22,23 routine 45:13 87:5 routinely 85:17,17 rush 37:22 38:6,7 38:10,12,14 39:10	39:11,12 rushed 117:18,18 s s 2:1 3:8 132:3 sarcoma 18:24 saw 29:1 101:18 saying 21:10 50:7 84:23 112:13 says 82:11 88:18 95:15 113:21 scan 61:7 90:9,10 91:23 scans 45:20 57:22 57:24 98:24 scheme 58:12 school 36:23 sciegen 4:6 scott 5:15 8:2,18 screen 8:20 61:11 85:7,8 92:4 93:7 125:5 127:3 screened 61:14 67:13,20,22 68:23 69:8 122:7 screening 50:23 51:4 55:23 56:4 56:19,24 57:4 58:9,17 59:4,6,7,9 59:12,19,21 60:2 60:19,21 61:2,8,16 61:18 62:1 65:9 65:11,19,22 67:15 68:14,22 69:11,14 69:20 70:12,17,21 71:4,15,19 73:6 74:1 83:3 87:3 92:1,12,14,14 93:1 97:13 98:1 109:23 110:5,8 121:16,19 122:2,9,11,12,15 122:17,22 123:8
--	---	--	---

[screening - state]

Page 21

123:16 126:4,11 screenings 125:21 screens 105:7 scripts 4:1 scroll 62:6 second 32:2 45:21 46:15 114:5 section 58:17 64:7 86:14 91:17 94:2 see 19:7 27:11 29:4,10 39:15 41:10 66:5 76:17 76:24 79:21 85:2 86:14 91:6,15 92:1 94:8 97:10 105:14 107:14,17 108:17,24,24 109:7 120:10 123:4,24 seeing 59:18,23 61:13 108:22 111:4 seen 28:22 48:20 72:19 76:11,12 87:4 101:15 self 25:22 send 111:20 115:22 sense 64:22 65:5,7 sent 33:24 116:3 131:14 sentence 80:13 82:6 september 34:6 set 30:8 32:14 58:6 63:5 127:21 130:1 seven 22:22,23 23:2 severe 47:6 73:23 sheet 131:11	shorter 117:19 shorthand 129:3 show 82:24 shown 33:12 84:24 86:21 88:14 112:14 shows 87:13 sick 52:10 sickle 26:3 sign 128:11 131:12 signature 130:6 signed 131:20 significance 26:1 109:14 significant 74:22 79:2 94:7 95:13 significantly 94:5 94:20 signs 93:15 similar 86:18 100:24 single 67:22 89:14 sir 45:21 95:2 99:15 sit 24:5 48:8 situation 42:14,17 45:6 52:8 58:3 73:1 123:21 124:20 situations 72:11 six 10:22 58:5 114:11 128:14 skokie 17:24 24:9 39:11 slater 43:22,23,24 44:4 slow 116:7 small 27:5 smear 81:6 93:24 smoke 109:22 111:7	smoker 70:8 90:18 90:21 smokers 61:1,3,5 society 87:21 soft 18:24 solco 4:13 sold 39:13 66:3 solid 27:1 solutions 8:3,11 20:4 131:23 solvents 19:15 somebody 33:23 44:3 47:7 54:8,10 56:21 57:22 59:9 62:2 70:8 78:24 82:24 95:8 97:18 126:8 someone's 33:16 59:8 75:23 soon 111:13 sorry 8:24 15:23 16:20,22 20:6 28:7 31:17 39:10 41:7,12 47:13 50:8 65:14 76:20 78:23 86:5 90:16 91:12 95:12 108:12 112:18 122:5 sort 99:19 120:11 sound 33:5 114:23 sounds 83:13,20 source 99:18 100:3,16 101:10 south 2:21 4:15 speak 41:9 120:5 speaking 11:22 86:4 105:2 speaks 94:11 specialized 86:14 92:20 110:11,15	110:21 specific 19:8,18 35:3 51:12 52:7 53:1 57:9 58:12 58:14,21 72:11 85:23 98:12 101:2 101:20,21 103:14 specifically 19:10 57:11,17 65:21 93:2 98:14 99:2 101:3 103:7 118:13 124:9 specifics 20:5 21:18 specified 129:16 speculation 96:7 spent 106:8 116:14,15 117:4 117:11 118:6,14 119:2,12 spoke 40:11 115:6 115:7 spoken 40:16 61:18 sponsoring 87:24 spung 4:2 ss 129:1 staff 24:17 stages 87:14 92:22 93:10 stand 126:15 standard 1:10 stands 50:18 start 36:22 111:11 111:12 started 8:18 28:12 starting 111:16 state 1:15 4:9 62:21,22 96:4 104:14,24 129:1,4
--	---	--	---

[stated - testimony]

Page 22

stated 62:22 82:23 95:5 96:3 statement 79:5 102:9 states 1:1 13:11 stating 96:5 statistic 48:2,2,3,6 statistically 74:22 status 52:9 53:21 54:5,6 55:1 72:4,6 steatosis 93:16 stenographer 11:4 11:11 stenographic 1:12 stereotype 129:9 sterilization 19:16 stick 96:4 stomach 17:7 27:5 stone 58:6 63:5 stopped 49:1 stoy 4:20 128:19 128:19 straightforward 54:7 street 2:4,9,21 4:9 4:15,21 5:3 stricken 95:19 strike 25:3 49:3 57:2 70:24 72:10 77:14 79:19 83:7 88:4 89:13 98:15 students 38:15 studies 45:19 54:24 57:9 74:23 92:19 112:10,10 112:14,23 study 24:21 subject 30:3 subscribed 133:14 substances 20:3 43:3 78:20	suffer 72:22 suffered 22:7 suffering 72:13 sufficient 74:11 suggest 112:15,17 112:19 suggested 51:17 87:22 suggesting 54:24 89:13 102:7 suggests 68:6 suite 1:16 2:10,16 2:22 3:4,16,21 4:4 5:3,9 supervise 39:2 support 47:19 72:16 86:23 100:23 104:11 supports 87:9 88:8 sure 11:14 13:15 15:8 21:7 41:15 46:12,14 52:19 54:22 57:1 58:24 59:19 61:12 68:21 70:16 71:13 76:20 94:13 98:18 100:2 102:20 103:24 104:3 107:19,19 113:11 surgery 57:23 surrounding 17:11 susceptible 46:5 swear 8:14 9:18 swedesford 3:3 sworn 8:16 10:1,4 10:24 129:6 133:14 symptom 58:15 symptomatic 58:20 59:5,8	symptoms 58:4,11 59:12 71:21 syndrome 25:21 45:1,9,22 46:4,5 46:18,20 47:4 49:14,22 50:10 52:21,24,24 60:22 109:9 t t 132:3,3 table 54:2 tainted 35:1 42:8 43:2,11 79:3 take 16:21 26:22 26:24 32:1 52:14 55:6 60:6 63:1 99:4 104:2 106:3 109:20 122:1 124:21 127:19 128:2 taken 1:13 10:18 12:3 16:9,14 17:3 18:14 21:17 26:4 48:18 60:11 89:20 99:9 114:9 122:21 129:15 talk 11:24 56:9 60:18 74:8 76:15 76:21 80:12 81:17 86:13,16 92:24 93:2 97:9 114:15 talked 56:1 91:22 103:20 107:6 talking 53:17 56:15 60:17 81:20 120:18 124:7 teach 39:4,6,7 teaching 38:6,17 team 32:22 teleconference 118:7	teleconferences 116:16 117:7 tell 10:24 11:15 12:4 16:12,17 24:20 33:9 36:7 36:10 42:5 43:19 56:18 57:4,4 63:9 63:16 77:14,16,18 82:5 91:10 95:8 103:24 114:15 telling 126:10 tells 123:18 ten 12:22 16:11 20:19 21:9 39:8 106:21 tend 21:11 tennessee 4:4 term 14:19 25:23 75:4,13,14 76:9,11 78:10 81:22 terminology 44:13 terminus 3:15 terms 53:16 56:23 56:23 58:9 59:5 tertiary 27:10 test 53:13 57:17 71:10,11,23 85:19 87:22 89:21 111:13,14 127:16 testified 10:5 14:11 16:13 49:5 60:20 115:10 testify 12:17 14:8 22:19 104:8 129:6 testifying 28:8 testimony 11:6 15:13 16:19,24 20:23 21:3,7 34:15,24 35:3,8,13 35:19 42:19 62:10 67:18 82:1 84:1
---	--	---	--

[testimony - two]

Page 23

84:20 89:7 92:6 103:18 110:24 115:11 129:8,12 131:9,18 133:8 testing 53:11 58:15 70:21 85:17 86:14,23 87:2,10 87:20 88:2,8 91:12 92:17,20 97:10 110:21 111:9 tests 57:10 64:15 80:2,15,18 83:3 85:21 87:6 92:14 93:6,17,19,23 98:12 110:9,10,20 112:1,2 121:21 122:4 teva 3:6,12 10:11 texas 3:22 thank 11:13 15:5 46:19 51:3 105:2 113:10 125:13 126:23 127:10 128:9 thanks 105:12 therapies 55:4 thing 28:19 57:20 66:16 92:17 113:24 things 19:19 21:12 25:24 45:22 50:5 50:9 54:18 64:20 69:13 70:5,6 73:13 75:8 76:2 77:8 79:1 80:12 81:14 92:9 93:5 93:14 103:19 110:8 112:3 121:23	think 13:7 14:16 14:16 15:14,15 22:24 28:6 34:18 36:2 41:11 43:11 44:8,10,13 45:23 49:5,16 50:5,9 52:20 54:23 60:20 61:1,9 62:5 63:4 69:6,11,12 70:7 71:1 72:10 78:17 81:14 82:14,24 84:15 89:23 92:2 95:22 97:19 106:8 106:10,17 108:4 115:6 118:23 119:18 120:24 125:17 127:24 thinking 12:23 third 117:3 118:2 thomas 2:20 thornburg 5:8 thought 113:6 three 10:22 16:14 23:1 29:2 32:12 54:12 55:1 58:4 60:9 106:5 113:22 113:23 threshold 75:15 75:21 76:8 83:9 85:20,24 thrombocytopenia 25:20 throw 21:12 thumb 7:6 103:21 tilt 101:18 time 1:10 8:5 9:12 9:16 14:17 16:8 17:8,21 22:10 23:24 27:9 28:1 29:1 32:7,11 34:3 35:15 38:4 39:12	60:8,12 63:1 75:13 76:12 81:22 89:3 99:6,10 103:18 104:2 106:7 110:16 113:10 114:6,10 116:14,16 117:4 117:17,20 118:6 119:9 128:13 129:15 131:19 timeframe 131:8 times 10:21,22,22 16:10,14 22:3,10 22:16,18,22,23,24 23:2,4,7,17 111:14 tissue 18:24 tobacco 60:3 70:9 75:9 110:1,6,19 today 28:5,9,15 29:11,15 31:18 62:13 today's 8:4 told 16:15 31:4 43:24 44:3,6 56:6 104:4 115:22 119:18 123:5 top 63:20 81:14 total 22:23 23:2 118:20 totally 54:8 touch 8:19 toxic 20:3 78:20 78:20 toxicity 75:10 toxins 18:19 76:1 tract 93:9 transcribed 129:10 transcript 1:12 6:1 11:5 128:18 131:6,20 133:5,8	transcription 129:12 transplantation 27:21 traurig 3:9,14 10:13 treat 55:23 107:20 108:12,12,14 110:18 120:19 121:11 124:15,17 treated 27:11 50:23 56:10 57:23 96:20 121:12 treating 17:13,20 50:1 51:15 56:21 89:24 123:22,23 treatment 18:9 27:12 52:4,13 53:16 54:15 58:3 treatments 27:20 51:18,20 53:24,24 55:2 tree 27:7 trials 51:22 true 58:7 63:4 69:14 129:11 133:8 truism 102:7 truth 10:24 129:6 129:7,7 truthfully 28:9 try 11:24,24 trying 42:19 105:6 tumor 57:12,13 tumors 27:1 turn 127:20 twelve 106:21 twenty 12:6 twice 45:11,12 two 9:17 32:8 47:3 54:3,12,12 92:9
---	--	--	--

[two - weigh]

Page 24

99:5 type 20:2 25:2 47:3 59:16 types 60:1 64:20 77:6,7 108:16 110:20 typographically 55:14 typos 55:15	university 37:1,5 37:9,22 38:6,8 39:10,13 unknown 61:23,24 unnecessary 126:14 upper 81:5 88:23 89:4,15 urinary 71:21 93:9 urine 110:9 usa 3:7,13 usage 125:4 use 51:17,19 54:6 54:23 55:3 63:16 64:1 74:10 75:13 95:8 usefulness 111:15 127:16 users 74:13 uspstf 109:23 usually 44:24 51:15,16 52:13 54:6 93:15 97:5 112:8 126:9 uterine 45:18 utilizing 87:22	82:14,21 83:4,9,15 83:22 84:11 101:22 102:18,22 122:21 123:15,20 124:4 128:3,7 131:4 132:1 133:1 vanderbilt 3:9 variants 109:13,14 various 19:6 35:21 45:6 vary 65:19 121:17 122:15,16 vast 78:18 vaughn 2:14 vcb 125:4 vegetables 77:12 verbally 11:11 verify 131:9 veritext 8:3,11 131:14,23 veritext.com 131:15 versus 49:22 56:20 57:5 vicinage 1:2 video 8:19 9:9 11:7 videoed 11:8 videographer 5:14 5:15 8:1,3,21 9:10 9:12 11:3 32:7 60:8 99:6 105:9 114:6 128:13 videotaped 1:7 28:15 view 56:19 vine 5:3 vitae 7:4 34:1 36:9	w wacker 1:15 8:6 walking 96:4 walks 56:12 want 9:10 11:19 11:23 14:21 25:15 31:11 32:5 36:15 36:17 41:8 42:18 46:7,10,12 55:9 60:18 80:12 89:4 103:14,21 104:2,3 108:20 113:16 wanted 18:20 33:9 41:19 114:14 122:8 wants 105:6 128:24 warn 11:23 warned 15:1 washington 2:10 13:12 way 11:1 28:2 30:6 43:2 50:3 78:13 79:11 85:8 85:12,13,15 93:7 102:20 105:17 114:2 117:21 119:21 122:7,10 122:23 wayne 3:4 ways 45:6 54:1 we've 36:6,7 51:23 55:8 56:1 60:7 61:17 64:5 74:5 101:1 103:20 104:10 110:8 125:11 wednesday 1:9,16 weeks 29:2 106:6 weigh 49:22
u	v		
ulmer 5:2 ulmer.com 5:5 ultimate 18:22 19:8 ultimately 13:5 22:8 42:10 45:16 89:23 ultrasounds 45:20 um 23:23 uncertain 25:24 109:14 unclear 108:4 uncommon 47:12 47:14 undergo 53:11 understand 11:6 21:7 58:24 61:12 67:17 69:3,3 89:11 103:3,13 105:20 121:3 125:24 understanding 42:24 65:12 76:5 76:6 78:17 understood 11:18 unique 27:17 56:10 72:24 93:5 122:4 united 1:1 13:11 universe 96:22	v 132:1 133:1 vague 53:7 78:7 84:6,12 85:10 87:11 96:1 100:21 107:22 124:2 valsartan 1:3 8:7 35:2 39:20,20 40:5,7,13,17 42:8 42:21,22,24 43:1,7 43:11 63:22 66:2 74:20 76:16,22 77:17 78:4,15 79:3,9 80:4 81:18		

[went - zoom]

Page 25

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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Exhibit 51

Page 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND MDL No. 2875
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

This Document Relates to All Actions

_____/

VIDEOTAPED

DEPOSITION OF: KALI PANAGOS, PHARM.D., R.PH

DATE: JANUARY 21, 2022

TIME: 9:32 a.m. - 5:52 p.m.

TAKEN BY: DEFENDANT

PLACE: RIVERO MESTRE LLP

2525 PONCE DE LEON BLVD. SUITE 1000

MIAMI, FL 33134

REPORTED BY: CHELSEA HLAVACH, NOTARY PUBLIC, STATE
OF FLORIDA

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<p>1 C. BRETT VAUGGN, ESQUIRE OF: Hollis Law Firm 2 8101 College Blvd, Suite 260 Overland Park, KS 66210 3 Attorney appeared via Zoom 4 DAN CAMPBELL, ESQUIRE 5 OF: Crowell & Moring 1001 Pennsylvania Avenue, NW 6 Washington, DC 20004 lbresnahan@crowell.com 7 Attorney appeared via Zoom 8 9 ALSO PRESENT 10 BEN PELTA-HELLER, Videographer, appeared via Zoom 11 JAVIER ORDONEZ, Videographer 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p>Page 7</p>	<p>1 2 3 4 5 6 7 8 9 10 11 12 13 * * * * * 14 S T I P U L A T I O N S 15 It is hereby stipulated and agreed by and between 16 counsel present for the respective parties, and the 17 deponent, that the reading and signing of the deposition 18 are hereby reserved. 19 20 21 22 23 24 25</p>	<p>Page 9</p>

Page 10	Page 12
<p>1 PROCEEDINGS</p> <p>2 * * * * *</p> <p>3 THE VIDEOGRAPHER: Good morning. We are going on</p> <p>4 the record at 9:32 a.m. on January 21st, 2022.</p> <p>5 This is Media Unit Number 1 of the video recorded</p> <p>6 deposition of Kali -- Dr. Kali Panagos. This</p> <p>7 deposition is being held at 2525 Ponce de Leon</p> <p>8 Boulevard, Suite 1000, in Miami, Florida.</p> <p>9 My name is Javier Ordonez and I am the</p> <p>10 videographer. The court reporter is Chelsea Hlavach;</p> <p>11 both from Veritext. Will the court reporter please</p> <p>12 swear in the witness?</p> <p>13 THE COURT REPORTER: Can we have counsel please</p> <p>14 state their appearances?</p> <p>15 THE VIDEOGRAPHER: Oh, can counsel please state</p> <p>16 your name and who you're -- I'm sorry. State your</p> <p>17 appearance and who you represent.</p> <p>18 MS. ISIDRO: Nilda Isidro from Greenberg Traurig</p> <p>19 on behalf of Teva.</p> <p>20 MR. KERNER: Glenn Kerner from Greenberg Traurig</p> <p>21 also on behalf of Teva.</p> <p>22 MR. HANSEL: Greg Hansel from Preti Flaherty on</p> <p>23 behalf of Maine Automobile Dealers Association.</p> <p>24 MR. WHARTON: Hi. Charlie Wharton on behalf of</p> <p>25 Plaintiffs.</p>	<p>1 right now, have there been any objections to the</p> <p>2 depositions being recorded on Zoom or has there been</p> <p>3 any agreement for this litigation to have the</p> <p>4 depositions recorded on Zoom? Because that was my</p> <p>5 understanding, but I'm asking the group.</p> <p>6 MS. ISIDRO: And further --</p> <p>7 MR. COTES: Glenn, it's Greg -- it's Greg Cotes.</p> <p>8 I mean, I've been on dozens and dozens of these in the</p> <p>9 past six months and I get that recording message every</p> <p>10 single time and no one's ever said a word about that.</p> <p>11 MS. ISIDRO: Yeah. I would also add that</p> <p>12 Plaintiffs have -- have raised objections to the</p> <p>13 number of folks in the room in person, and this was</p> <p>14 something that was discussed at the recent status</p> <p>15 conference, and that is also part of the reason why</p> <p>16 there is the Zoom setup, just in light of the pandemic</p> <p>17 and concerns about safety that have been raised by</p> <p>18 Plaintiffs, just as much as by anyone else.</p> <p>19 And so, again, I don't see the -- the problem</p> <p>20 with recording the Zoom consistent with all of that.</p> <p>21 MR. HANSEL: Okay. All right. In that case</p> <p>22 we'll -- we'll allow it.</p> <p>23 MS. ISIDRO: Thank you.</p> <p>24 THE COURT REPORTER: Okay. Will you raise your</p> <p>25 right hand, please?</p>
Page 11	Page 13
<p>1 MS. WHITELEY: Conlee Whiteley on behalf of</p> <p>2 Plaintiffs.</p> <p>3 MR. HANSEL: Before we go on the record further,</p> <p>4 I guess I have a couple of preliminaries. First,</p> <p>5 Jorge Mestre is also here, Chelsea, on behalf of the</p> <p>6 Plaintiffs.</p> <p>7 And I see I'm being asked on the Zoom to agree</p> <p>8 that this be recorded on Zoom, and I don't think</p> <p>9 that's necessary because we have a videographer and a</p> <p>10 court reporter. So I would request that the Zoom not</p> <p>11 be recorded.</p> <p>12 MS. ISIDRO: The Zooms, I believe, have been</p> <p>13 recorded at prior depositions, and in the event anyone</p> <p>14 on Zoom asks questions, et cetera, that's -- that's</p> <p>15 part of the purpose of -- of the Zoom recording, is my</p> <p>16 understanding.</p> <p>17 MR. HANSEL: That would also be audible in the</p> <p>18 room and would be picked up on the video, the</p> <p>19 videographer, the court -- the official videographer,</p> <p>20 as well as by the court reporter.</p> <p>21 Is that really necessary?</p> <p>22 MR. KERNER: Well, let me just ask you a quick</p> <p>23 question. My understanding is that the prior</p> <p>24 depositions have all been recorded on Zoom as well,</p> <p>25 and this is for you folks and anybody actually on Zoom</p>	<p>1 Do you swear or affirm the testimony you are</p> <p>2 about to give in this matter will be the truth, the</p> <p>3 whole truth, and nothing but the truth?</p> <p>4 THE WITNESS: I do.</p> <p>5 KALI PANAGOS, PHARM.D., R.PH,</p> <p>6 having been first duly sworn, was examined and</p> <p>7 testified as follows:</p> <p>8 DIRECT EXAMINATION</p> <p>9 BY MS. ISIDRO:</p> <p>10 Q. Good morning, Dr. Panagos.</p> <p>11 A. Good morning.</p> <p>12 Q. My name is Nilda Isidro. I'm with the law firm</p> <p>13 of Greenberg Traurig and I represent Defendant, Teva.</p> <p>14 A. Uh-huh.</p> <p>15 Q. We're just meeting for the first time this</p> <p>16 morning, correct?</p> <p>17 A. Yes, we are.</p> <p>18 Q. Can you please state your full name for the</p> <p>19 record?</p> <p>20 A. My full name is Dr. Kali Panagos.</p> <p>21 Q. And what is your current professional address?</p> <p>22 A. My current professional address is 105 Down</p> <p>23 Court, Windermere, Florida -- Florida.</p> <p>24 Q. Thank you. Where do you currently reside?</p> <p>25 A. New York.</p>

<p style="text-align: right;">Page 14</p> <p>1 Q. Have you ever been deposed before?</p> <p>2 A. No, I have not.</p> <p>3 Q. Okay. So I'll just go over a few ground rules on</p> <p>4 how -- on how this works --</p> <p>5 A. Sure.</p> <p>6 Q. -- since this is your first deposition.</p> <p>7 As you can see there's a court reporter to your</p> <p>8 right who's taking down everything that we say.</p> <p>9 A. Uh-huh.</p> <p>10 Q. So for that reason, it's very important that you</p> <p>11 answer verbally, meaning yes -- saying yes or no rather</p> <p>12 than nodding your head or saying --</p> <p>13 A. I understand.</p> <p>14 Q. -- uh-huh or huh-uh, and for that same reason,</p> <p>15 it's important that -- that we not talk over each other,</p> <p>16 right? So that you wait that -- until I finish my question</p> <p>17 before you start to answer, and I'll do the same. I'll try</p> <p>18 to wait until you finish your answer before I start the</p> <p>19 next question, just so that the court reporter isn't trying</p> <p>20 to take both of us -- what both of us are saying down at</p> <p>21 the same time. Is that all right?</p> <p>22 A. That's right.</p> <p>23 Q. Great. As -- as you've seen this morning, there</p> <p>24 are some folks who are also on Zoom and so there's that</p> <p>25 setup as well. There you may hear -- you may hear</p>	<p style="text-align: right;">Page 16</p> <p>1 that?</p> <p>2 A. No.</p> <p>3 Q. Okay. And do you want to read and sign this</p> <p>4 deposition?</p> <p>5 A. Sure.</p> <p>6 Q. Okay. Now, Doctor, you're appearing here today</p> <p>7 pursuant to a notice of deposition; is that right?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. We're going to go ahead and mark that</p> <p>10 notice of deposition as Exhibit 1. And, again, as I</p> <p>11 mentioned, because of the Zoom, someone's going to be</p> <p>12 loading these exhibits up on the Zoom as well, so we may</p> <p>13 just give a little bit of a pause when we mark an exhibit</p> <p>14 so that they can get caught up as well.</p> <p>15 (Exhibit No. 1 was marked for identification.)</p> <p>16 All right. Doctor, have you seen this document</p> <p>17 before?</p> <p>18 A. No.</p> <p>19 Q. Okay. I'm going to ask you to take a look at</p> <p>20 Page 6. There are a number of requests there. And just if</p> <p>21 you could take a look at those and let me know, did anyone</p> <p>22 ask you whether you had any of these documents that are</p> <p>23 requested here in your possession?</p> <p>24 MR. HANSEL: I'm going to object on grounds of</p> <p>25 work product privilege to any requests for</p>
<p style="text-align: right;">Page 15</p> <p>1 objections or something coming from Zoom. You may also</p> <p>2 later today get questions from folks on -- on -- on the</p> <p>3 Zoom.</p> <p>4 If at any time you don't understand my question,</p> <p>5 please let me know. If you don't hear my question, please</p> <p>6 let me know. If -- however, if you do answer my question,</p> <p>7 I'm -- I'm going to take that to mean that you understood</p> <p>8 my questions. Is that fair?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. If at any time you need to take a break,</p> <p>11 just let me know and -- and we can do that. I would just</p> <p>12 ask that if there's a question pending, that that question</p> <p>13 be answered before we go on a break.</p> <p>14 A. Okay.</p> <p>15 Q. Do you have any questions about the -- how</p> <p>16 this -- about how -- the procedures or how this will work</p> <p>17 today?</p> <p>18 A. Not at this time.</p> <p>19 Q. Okay. And as you know you're here to testify</p> <p>20 under oath. Is there any reason that you would not -- you</p> <p>21 would not be able to give truthful and accurate testimony</p> <p>22 today?</p> <p>23 A. No.</p> <p>24 Q. You're not on any medications that might</p> <p>25 interfere with your ability to testify or anything like</p>	<p style="text-align: right;">Page 17</p> <p>1 communications between counsel and the witness as, you</p> <p>2 know, we have also responded to this request in</p> <p>3 writing, as you know.</p> <p>4 MS. ISIDRO: I'll rephrase my question.</p> <p>5 BY MS. ISIDRO:</p> <p>6 Q. Prior to the deposition today, did you check</p> <p>7 whether you had any of the documents that are listed in</p> <p>8 these requests in your possession?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. We're going to go through them one by one.</p> <p>11 A. Sure.</p> <p>12 Q. And -- and we'll talk about each one. So the</p> <p>13 first one is your current up-to-date resume or CV. There</p> <p>14 was a CV attached as an exhibit to your report, correct?</p> <p>15 A. Correct.</p> <p>16 Q. Is that your current CV?</p> <p>17 A. Yes.</p> <p>18 Q. Since -- since producing your report, have --</p> <p>19 have there been any updates to the information on that CV?</p> <p>20 A. No.</p> <p>21 Q. Okay. Let's go ahead and mark that CV as Exhibit</p> <p>22 Number 2 and then we'll go through later on the rest of the</p> <p>23 items on this list.</p> <p>24 (Exhibit No. 2 was marked for identification.)</p> <p>25 Okay. Doctor, so it notes on your CV that you</p>

Page 18	Page 20
<p>1 received a bachelor of science from St. John's University</p> <p>2 in 1997; is that right?</p> <p>3 A. Yes.</p> <p>4 Q. What was your major?</p> <p>5 A. Biology.</p> <p>6 Q. Did you have any minors?</p> <p>7 A. Computer science.</p> <p>8 Q. How long did it take you to complete that</p> <p>9 bachelor of science?</p> <p>10 A. Four years.</p> <p>11 Q. And then after that you pursued a second</p> <p>12 bachelor's degree; is that right?</p> <p>13 A. Yes.</p> <p>14 Q. That was from St. John's University in 2000?</p> <p>15 A. Yes.</p> <p>16 Q. What was your major then?</p> <p>17 A. Pharmacy.</p> <p>18 Q. And did you have any minors at that time?</p> <p>19 A. No.</p> <p>20 Q. How long did it take you to complete that</p> <p>21 bachelor's degree?</p> <p>22 A. That was completed in 2000.</p> <p>23 Q. When did you -- when did you begin pursuing that</p> <p>24 bachelor's degree?</p> <p>25 A. In '97.</p>	<p>1 curriculum of the pharmacy program, the pharmacy advisors</p> <p>2 reported to me with regards to students -- student</p> <p>3 advisement for coursework in the pharmacy program, and I</p> <p>4 also evaluated student progress for remaining and -- within</p> <p>5 the program as well.</p> <p>6 Q. Okay. And did you have any other titles or roles</p> <p>7 within the Long Island University?</p> <p>8 A. Yes, I served as an adjunct faculty in the</p> <p>9 department of social sciences.</p> <p>10 Q. From --</p> <p>11 A. In the pharmacy program.</p> <p>12 Q. From what year to what year?</p> <p>13 A. 2000 and -- jeez. I was -- 2005 about until</p> <p>14 2009.</p> <p>15 Q. Okay. Did you teach classes as part of that</p> <p>16 role?</p> <p>17 A. I certainly did.</p> <p>18 Q. What classes did you teach?</p> <p>19 A. I taught pharmacy orientation, which is an</p> <p>20 introduction course to pharmacy. I also taught or was part</p> <p>21 of the recitation courses, which are laboratory type</p> <p>22 courses in the social sciences division of pharmacy</p> <p>23 program.</p> <p>24 Q. Okay. Any other courses that you taught?</p> <p>25 A. No.</p>
Page 19	Page 21
<p>1 Q. Okay. And -- and then you received a doctorate</p> <p>2 from Shenandoah University in 2006?</p> <p>3 A. Yes.</p> <p>4 Q. That was also in pharmacy?</p> <p>5 A. That was a doctorate in pharmacy, yes.</p> <p>6 Q. Okay. And when did you begin pursuing that</p> <p>7 doctorate?</p> <p>8 A. Two years prior to the graduation date.</p> <p>9 Q. Have you had any other formal education beyond</p> <p>10 those degrees that we've just discussed?</p> <p>11 A. No.</p> <p>12 Q. Okay. So in 2002 you joined the Long Island</p> <p>13 University's faculty; is that right?</p> <p>14 A. Yes.</p> <p>15 Q. And you were on that faculty until 2009?</p> <p>16 A. Yes, I was part of the faculty and administration</p> <p>17 till 2009.</p> <p>18 Q. What -- what was your first role within Long</p> <p>19 Island University's faculty and administration?</p> <p>20 A. Director of pharmacy services.</p> <p>21 Q. And how long did you hold that position?</p> <p>22 A. I held that until, you know, 2009.</p> <p>23 Q. Okay. What were your roles and responsibilities</p> <p>24 under that title?</p> <p>25 A. My roles and responsibilities were to oversee the</p>	<p>1 Q. And other than these two roles that we've just</p> <p>2 discussed, did you have any other roles or titles within</p> <p>3 the Long Island University?</p> <p>4 A. No.</p> <p>5 Q. You're currently a registered pharmacist in the</p> <p>6 State of New York?</p> <p>7 A. Yes, I am.</p> <p>8 Q. Are you registered or licensed as a pharmacist in</p> <p>9 any other state?</p> <p>10 A. No.</p> <p>11 Q. Do you have any other certifications --</p> <p>12 professional certifications or qualifications?</p> <p>13 A. I do.</p> <p>14 Q. What are they?</p> <p>15 A. I have an immunizer certification; I am certified</p> <p>16 in first aid or CPR for infant, child, and adults; I am</p> <p>17 also certified as an MTM pharmacist; and I also have a New</p> <p>18 York State Department Adjuster License as well.</p> <p>19 Q. Okay. You mentioned an immunizer certification.</p> <p>20 What does that -- what does that mean?</p> <p>21 A. That means I am permitted to administer</p> <p>22 immunizations to patients.</p> <p>23 Q. And what is an MTM pharmacist?</p> <p>24 A. Medication therapy management.</p> <p>25 Q. What -- what does medication therapy management</p>

<p style="text-align: right;">Page 22</p> <p>1 entail?</p> <p>2 A. It entails being able to counsel patients on</p> <p>3 their -- the drugs that they're on and their overall</p> <p>4 profile and provide them guidance for compliance and</p> <p>5 adherence.</p> <p>6 Q. What do you mean by compliance and adherence?</p> <p>7 A. So that they know how to properly take their</p> <p>8 medication, what the medication is for, and review with</p> <p>9 them the -- their overall drug profile.</p> <p>10 Q. And then you also mentioned New York State</p> <p>11 Department Adjuster. What does that entail?</p> <p>12 A. At this time I don't have any requirements that</p> <p>13 it -- that I'm required for that, so it's there, but I</p> <p>14 don't have any requirements for it.</p> <p>15 Q. What does a New York State Department Adjuster</p> <p>16 do?</p> <p>17 A. That is used in the managed care field or in the</p> <p>18 pharmacy management or if you needed to -- it's more on the</p> <p>19 business side. So it's not directly patient care. It's on</p> <p>20 the business side of the pharmacy.</p> <p>21 Q. What does that mean, more on -- more on the</p> <p>22 business side? What types of things?</p> <p>23 A. The organization I was employed with, Broadreach</p> <p>24 Medical Resources, it was beneficial to them if I had this</p> <p>25 adjuster license.</p>	<p style="text-align: right;">Page 24</p> <p>1 clinical affiliation in pain management and anesthesia at</p> <p>2 the Hospital for Special Surgery, correct?</p> <p>3 A. That is correct.</p> <p>4 Q. What does that position entail?</p> <p>5 A. That position required me to participate and</p> <p>6 understand the functions of anesthesiology and pain</p> <p>7 management of patients as it regards to their procedures</p> <p>8 that they were -- with regards to their procedures that</p> <p>9 they were having and work closely with the anesthesia team</p> <p>10 and pain management -- management team for management of</p> <p>11 that patient while they were in the hospital.</p> <p>12 Q. Did you have any sort of patient facing role in</p> <p>13 that position?</p> <p>14 A. The patients were in surgery, so I was in the</p> <p>15 surgery room with the anesthesiologists and then we would</p> <p>16 visit the patient in the post-op.</p> <p>17 Q. Okay. You didn't -- you didn't prescribe any</p> <p>18 medication or anything like that, correct?</p> <p>19 A. No, I did not.</p> <p>20 Q. Do you have the ability to prescribe medication?</p> <p>21 A. No, I do not.</p> <p>22 Q. Okay. And during what time did you have that</p> <p>23 clinical affiliation?</p> <p>24 A. That was during my time at St. John's pursuing</p> <p>25 the pharmacy -- my bachelor's of pharmacy degree.</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. In what way was it beneficial?</p> <p>2 A. To adhere with requirements by New York State for</p> <p>3 the -- their type of business.</p> <p>4 Q. What responsibilities did you have with that</p> <p>5 employer as -- as an adjuster?</p> <p>6 A. My responsibilities to that employer were in the</p> <p>7 capacity of a clinical pharmacist and director of clinical</p> <p>8 operations, as well as client oversight as well.</p> <p>9 Q. Okay. I'm just trying to understand how the --</p> <p>10 the New York State Department Adjuster certification comes</p> <p>11 into play.</p> <p>12 A. Uh-huh.</p> <p>13 Q. What it allows you to do that you wouldn't be</p> <p>14 able to do if you had -- if you did not have that</p> <p>15 certification.</p> <p>16 A. It allows the organization to adhere with the</p> <p>17 requirements of New York State by having an adjuster's</p> <p>18 license -- an employee with an adjuster's license on staff.</p> <p>19 Q. Now, you also mentioned certain clinical</p> <p>20 affiliations in your CV?</p> <p>21 A. Yep.</p> <p>22 Q. And -- and those -- one of those is with Hospital</p> <p>23 of Special Surgery, correct?</p> <p>24 A. Correct.</p> <p>25 Q. You mention in your report that you have a</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. Okay. And then you also list a clinical</p> <p>2 affiliation with Bellevue Medical Center.</p> <p>3 A. Yes.</p> <p>4 Q. And during what time did you hold that clinical</p> <p>5 affiliation?</p> <p>6 A. That clinical affiliation was done during my time</p> <p>7 pursuing my doctorate degree in pharmacy.</p> <p>8 Q. Okay. And what was your role with Bellevue</p> <p>9 Medical Center?</p> <p>10 A. My primary role was participation in the lipid</p> <p>11 and anticoagulation clinics, participation with the medical</p> <p>12 and pharmacy teams there to manage patients.</p> <p>13 Q. And then you've also listed a clinical</p> <p>14 affiliation with Northwell Health University.</p> <p>15 A. Correct.</p> <p>16 Q. During what time frame did you hold that clinical</p> <p>17 affiliation?</p> <p>18 A. That affiliation was done during my time at</p> <p>19 St. John's University pursuing the bachelor's of pharmacy</p> <p>20 degree.</p> <p>21 Q. And what was your role with Northwell Health?</p> <p>22 A. That was an internal medicine rotation with a</p> <p>23 focus on diabetes, participating in medical rounds and with</p> <p>24 physicians and pharmacists to manage patients with</p> <p>25 different diagnoses and conditions for which they were in</p>

<p style="text-align: right;">Page 26</p> <p>1 the hospital.</p> <p>2 Q. And, finally, you list as -- under clinical</p> <p>3 affiliations, advisory panel member, AMGEN for Repatha?</p> <p>4 A. Correct.</p> <p>5 Q. During what time frame did you hold that</p> <p>6 position?</p> <p>7 A. 2019.</p> <p>8 Q. And what were your roles and responsibilities as</p> <p>9 an advisory panel member?</p> <p>10 A. I was asked to participate in the advisory panel</p> <p>11 for evaluation of Repatha and discussion about the use of</p> <p>12 the drug and -- in all capacities.</p> <p>13 Q. What type of drug is Repatha?</p> <p>14 A. Repatha is a lipid lowering drug or</p> <p>15 hypercholesterolemia drug intended for certain populations</p> <p>16 that meet the criteria for intended use.</p> <p>17 MR. MESTRE: If you're taking a pause, I just</p> <p>18 wanted to make my appearance. Jorge Mestre on behalf</p> <p>19 of the Plaintiffs. And I also wanted to make sure</p> <p>20 that we're not recording on the Zoom, correct?</p> <p>21 MR. KERNER: We are and we had that discussion.</p> <p>22 MR. MESTRE: Oh, we did?</p> <p>23 MS. ISIDRO: We had that discussion already.</p> <p>24 Yes.</p> <p>25 MR. MESTRE: Okay. Okay.</p>	<p style="text-align: right;">Page 28</p> <p>1 verifying that that is the right medication, the right</p> <p>2 patient, and ensuring that there aren't any</p> <p>3 contraindications for the -- for the patient so.</p> <p>4 Q. And during part of this same time period you also</p> <p>5 worked at Broadreach Medical Resources; is that right?</p> <p>6 A. Correct.</p> <p>7 Q. That was from 2008 to 2018?</p> <p>8 A. Correct.</p> <p>9 Q. And what was your role at Broadreach?</p> <p>10 A. I had several roles -- roles there. I was a</p> <p>11 clinical pharmacist and then became the director of</p> <p>12 clinical operations and also the head of client management</p> <p>13 as well.</p> <p>14 Q. From what year to what year were you a clinical</p> <p>15 pharmacist at Broadreach?</p> <p>16 A. The entire time.</p> <p>17 Q. And from what year to what year were you director</p> <p>18 of clinical operation?</p> <p>19 A. As it states in my CV, 2008 through 2018.</p> <p>20 Q. So for the full time period?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. And from what year to what year were you</p> <p>23 head of account services and client management?</p> <p>24 A. It was a couple years later so 2009 or 2010.</p> <p>25 Shortly thereafter.</p>
<p style="text-align: right;">Page 27</p> <p>1 MR. KERNER: And your co-counsel noted your</p> <p>2 appearance earlier as well.</p> <p>3 MR. MESTRE: Thank you.</p> <p>4 BY MS. ISIDRO:</p> <p>5 Q. Dr. Panagos, you worked as a pharmacist at</p> <p>6 Walgreens in New York from 2000 to 2015; is that correct?</p> <p>7 A. That is correct.</p> <p>8 Q. Were you the lead pharmacist during that time?</p> <p>9 A. I was a staff pharmacist.</p> <p>10 Q. Okay. Besides staff pharmacist, did you ever</p> <p>11 have any other roles with Walgreens?</p> <p>12 A. No.</p> <p>13 Q. What were your duties and responsibilities as a</p> <p>14 staff pharmacist?</p> <p>15 A. To manage the pharmacy, so that's all aspects of</p> <p>16 the pharmacy at the time where I'm assigned, my hours of</p> <p>17 work, and so that includes the prescriptions, filling the</p> <p>18 prescriptions, reviewing, filling, dispensing, and</p> <p>19 counseling the -- the prescriptions that are coming in and</p> <p>20 for the patients that are coming in.</p> <p>21 I also supervise the technicians that are working</p> <p>22 in the pharmacy during that time. They fall under my</p> <p>23 supervision, including the interns that are on shift at the</p> <p>24 same time as I am. I'm also responsible that the drug</p> <p>25 product is the correct drug product is being filled and</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. Okay. So within a couple of years of starting at</p> <p>2 Broadreach through the end of your time there?</p> <p>3 A. Correct.</p> <p>4 Q. Okay. What was the split on your time between</p> <p>5 Broadreach and Walgreens during this time frame?</p> <p>6 A. I began my time with Broadreach initially</p> <p>7 part-time.</p> <p>8 Q. Uh-huh.</p> <p>9 A. And I was also part-time or per diem -- well,</p> <p>10 part-time with Walgreens at that time.</p> <p>11 Q. What were your duties and responsibilities as a</p> <p>12 clinical pharmacist -- pharmacist at Broadreach?</p> <p>13 A. My duties included review of prior authorization</p> <p>14 requests, collaboration with prescribers as needed on</p> <p>15 behalf of those requests, collaboration with -- or outreach</p> <p>16 to patients as needed on behalf of those requests. So</p> <p>17 review of the prior authorization, completing that request,</p> <p>18 documenting the results or the findings, tracking that, and</p> <p>19 communicating appropriately.</p> <p>20 Q. What were your roles and responsibilities as</p> <p>21 director of clinical operations at Broadreach?</p> <p>22 A. My roles and responsibilities as clinical</p> <p>23 operations included ensuring that management of the</p> <p>24 formulary, management of the prior authorizations,</p> <p>25 management of every clinical aspect with regards to the</p>

<p style="text-align: right;">Page 30</p> <p>1 prescription benefit was done efficiently in a proper 2 workflow. 3 Q. And what were your roles and responsibilities as 4 head of client services and account management at 5 Broadreach? 6 A. My roles and responsibilities included advising 7 patient -- clients on all aspects of their pharmacy 8 program, which includes their formulary, their plan design, 9 drugs covered and not covered, and providing them with 10 guidance on how to best do that. 11 Q. Your CV states that you developed industry 12 exclusive prescription indemnity/reference based program 13 during your time at Broadreach. Can you tell us more about 14 that, what that entailed? 15 A. That is a prescription type program that is -- 16 takes a subset of drugs and applies -- creates a -- a plan 17 that clients or employers may choose if it's appropriate 18 for their employees as a prescription drug offering. It is 19 structured to allow kind of a different option for 20 employers to take for prescription benefits. 21 Q. And what was your role in developing that 22 program? 23 A. My role in developing that program included 24 choice of the medications that would be part of the product 25 offering and that includes both brands and generics, and</p>	<p style="text-align: right;">Page 32</p> <p>1 in terms of an evidence-based guidelines? 2 A. The guidelines set forth by the medical community 3 for treatment of a patient with a diagnosis of asthma. 4 Q. And for the other conditions that you mentioned, 5 is it the same -- 6 A. The same. 7 Q. Okay. Your CV also states that you manage 8 integration of data across medical and prescription, 9 including population, health, and enrollment analytics? 10 A. Correct. 11 Q. Can you tell us more about what that entailed? 12 A. Yes. My role included review and analysis of the 13 data that -- both on the prescription side and where 14 available on the medical side and being able to evaluate 15 that on behalf of our clients. 16 Q. What do you mean by the data on the prescription 17 side? 18 A. Claims data. 19 Q. And what do you mean by the data on the medical 20 side? 21 A. Likewise. 22 Q. Where would you get that data? 23 A. The data would come from the PBM or the medical 24 carrier. 25 Q. And finally your CV states that you served as</p>
<p style="text-align: right;">Page 31</p> <p>1 how those medications would be structured within that 2 program for tiering or payments, et cetera. 3 Q. Your CV also states that you designed evidence 4 based market competitive clinical programs with documented 5 ROI. Can you tell us what that refers to? 6 A. Sure. Clinical programs are a part of a pharmacy 7 benefit offering and they are designed based on evidence 8 based guidelines, which are accepted in the healthcare 9 community as how you -- patients would be treated according 10 to the conditions that they have. So when you create a 11 clinical program, you do so on clinical merit but in the -- 12 you structure it on clinical merit, but you also 13 incorporate other components essential to the prescription 14 drug benefit to help clients manage their population 15 and -- and it's linked to the formulary. 16 Q. You referenced some evidence-based guidelines. 17 Are there specific evidence-based guidelines that you used 18 in putting together those programs? 19 A. Yes. 20 Q. Which ones? 21 A. There were many. 22 Q. Can you give some examples? 23 A. Asthma, diabetes, cardiovascular, just to name a 24 few. There are many. 25 Q. So when you say asthma, what does that refer to</p>	<p style="text-align: right;">Page 33</p> <p>1 subject matter expert on all PBM clinical drug and 2 specialty items. 3 A. That is correct. 4 Q. What did you mean by served as a subject matter 5 expert on PBMs? 6 A. So for our clients and -- I was the person who 7 they would come to for questions about determining -- any 8 question on PBM, actually. So I served as a subject matter 9 expert to advise on PBM and yeah. 10 Q. And those clients were -- not -- not specific 11 names, but, you know, what -- what type of entities -- 12 A. Self-insured -- 13 Q. -- were those clients? 14 A. -- clients, self-insured employer groups. 15 MR. HANSEL: Please remember to let her finish 16 her question before you begin your answer. 17 THE WITNESS: Okay. Thank you. 18 BY MS. ISIDRO: 19 Q. And what do you mean by served as a subject 20 matter expert on clinical, drug, and specialty items? 21 A. Again, I would provide guidance and advisement on 22 drugs that are -- were on the formulary or even not on the 23 formulary. I'd provide the -- would answer any questions 24 related to those drugs. 25 Q. What does the clinical refer to?</p>

<p style="text-align: right;">Page 34</p> <p>1 A. The clinical refers to the medication and the use 2 of the medication from my background and experience as a 3 pharmacist of being able to provide that thought process 4 around the discussion of the medication. 5 Q. And what do you mean by specialty items? 6 A. Specialty medications are part of a formulary and 7 they are -- there's -- there's no universal accepted 8 definition for specialty but they're -- tend to be for more 9 complex conditions. 10 Q. Is that what you're referring to when you use 11 that term in your CV? 12 A. Correct. 13 Q. Okay. You also spent it seems like a year or 14 maybe less than a year at Smith Rx in San Francisco; is 15 that right? 16 A. That is right. 17 Q. How -- how -- what is the precise amount of time 18 that you spent at Smith Rx? 19 A. I think it was from February to December. Yeah. 20 Q. What was your role or roles within Smith Rx? 21 A. Director of clinical services. 22 Q. That was the only role you held there? 23 A. Yes. 24 Q. What were your -- your responsibilities under 25 that role?</p>	<p style="text-align: right;">Page 36</p> <p>1 industry experts, industry colleagues. Yeah. 2 Q. You're the founder of AristaRx Wellness; is that 3 right? 4 A. That is right. 5 Q. And you began that in 2018 as well? 6 A. Correct. 7 Q. What is AristaRx Wellness? 8 A. AristaRx Wellness is my LLC that I created. 9 Q. What does -- what services does AristaRx Wellness 10 offer? 11 A. Pharmacy benefit consulting. 12 Q. And to whom do you offer that pharmacy benefit 13 consulting? 14 A. To primarily self-insured employer groups but 15 could be any group that needs pharmacy benefit consulting. 16 Q. Do you have any employees? 17 A. No. 18 Q. Are you the sole member of that LLC? 19 A. Yes. 20 Q. And what are your duties and responsibilities 21 within AristaRx Wellness? 22 A. To provide pharmacy benefit consulting to my 23 clients. 24 Q. Is that still an active company? 25 A. Yes.</p>
<p style="text-align: right;">Page 35</p> <p>1 A. To set up the pharmacy benefits with regards to 2 formulary, prior authorization, reviews to ensure that 3 those were done appropriately and manage the formulary. 4 Q. Why did you leave that position? 5 A. There are several reasons. One, distance from my 6 home. 7 Q. Your home was in New York at that time? 8 A. Correct. 9 Q. What were some of the other reasons? 10 A. Primarily distance from my home. 11 Q. And you've been on the Council of Strategic 12 Healthcare Advisors since 2018? 13 A. Yes. 14 Q. What are your roles and responsibilities there? 15 A. They call upon my expertise as needed for cases 16 or surveys, clinical related items for which they deem my 17 qualification's appropriate for response. 18 Q. Who are you advising in that role? 19 A. Whatever the particular project at that time 20 calls for, who -- whomever that may be. 21 Q. What -- are these -- are these all different 22 types of business entities? 23 A. It could be. 24 Q. What else could it be? 25 A. It could be other healthcare professionals,</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. And the business address that you gave earlier 2 here in Florida, is that for AristaRx Wellness? 3 A. No. 4 Q. Okay. What entity was that address for? 5 A. ARMSRx. 6 Q. ARMSRx. And you've been with ARMSRx since 2019? 7 A. Yes. 8 Q. What is -- what roles have you held within 9 ARMSRx? 10 A. Senior vice president and executive vice 11 president. 12 Q. And during what time frame were you senior vice 13 president? 14 A. 2019 through 2021, as listed on my CV. 15 Q. And executive vice president during what time 16 frame? 17 A. 2021 till present. 18 Q. Okay. What were your roles and responsibilities 19 as senior VP? 20 A. To provide advice and guidance to our clients 21 with regards to their pharmacy benefit program, all aspects 22 of their pharmacy benefit program. 23 Q. And what are your roles and responsibilities as 24 executive vice president? 25 A. To provide advisement and guidance to our clients</p>

<p style="text-align: right;">Page 38</p> <p>1 with respect to their pharmacy benefit program, all</p> <p>2 aspects, and I also oversee or have individuals within our</p> <p>3 organization who report up to me.</p> <p>4 Q. Okay. So you didn't have individuals who</p> <p>5 reported up to you as a senior VP?</p> <p>6 A. I -- right.</p> <p>7 Q. Okay.</p> <p>8 A. They -- they report up to me now.</p> <p>9 Q. Okay. Was that the only way in which your role</p> <p>10 changed from senior VP to executive VP?</p> <p>11 A. Yes.</p> <p>12 Q. How many people report to you as EVP at ARMSRx?</p> <p>13 A. Two.</p> <p>14 Q. And what are their roles?</p> <p>15 A. They are in account management and PBM</p> <p>16 operations.</p> <p>17 Q. Doctor, you mention in your report that you have</p> <p>18 20 years of experience, half of which has been dedicated to</p> <p>19 the managed care and pharmacy consulting industry</p> <p>20 overseeing clinical development, overall PBM operations,</p> <p>21 and client services/management, working primarily with</p> <p>22 self-insured clients, third-party administrators, and TPPs;</p> <p>23 is that right?</p> <p>24 A. That is right.</p> <p>25 Q. What is a TPP?</p>	<p style="text-align: right;">Page 40</p> <p>1 the confines of their organization.</p> <p>2 Q. Okay. What is a TPA?</p> <p>3 A. Third-party administrator.</p> <p>4 Q. What does a third-party administrator do?</p> <p>5 A. They would administer the benefits, you know, on</p> <p>6 behalf of an entity or a group.</p> <p>7 Q. And how does that differ from a TPP, if at all?</p> <p>8 A. So the third-party payer has ultimate</p> <p>9 responsibility for -- at risk for those claims. A TPA will</p> <p>10 manage the claims processing and the functions associated</p> <p>11 with the benefit but may not have ultimate responsibility</p> <p>12 or at risk for the claims.</p> <p>13 Q. Okay. Now, I see you have a few documents in</p> <p>14 front of you right now. One of them is Exhibit 1, another</p> <p>15 one is Exhibit 2, but it looks like you might have a few</p> <p>16 other documents as well; is that right?</p> <p>17 A. Yes.</p> <p>18 Q. What are the other documents that you have in</p> <p>19 front of you?</p> <p>20 A. My statement, my opinion, my expert report.</p> <p>21 Q. Okay. Anything else that you have in front of</p> <p>22 you right now?</p> <p>23 A. Not document-wise.</p> <p>24 Q. Okay. And this copy of your expert report is one</p> <p>25 that you've brought with you today, yourself?</p>
<p style="text-align: right;">Page 39</p> <p>1 A. A third-party payer.</p> <p>2 Q. And can you describe what a third-party payer is</p> <p>3 or does?</p> <p>4 A. They are responsible for reimbursement or</p> <p>5 management of the health care claims, including the</p> <p>6 prescription benefit.</p> <p>7 Q. And how, if at all, is a TPP different from a</p> <p>8 self-insured employer?</p> <p>9 MR. HANSEL: Object to the form.</p> <p>10 A. Could you be more specific?</p> <p>11 BY MS. ISIDRO:</p> <p>12 Q. Are there any ways in which a TPP differs from a</p> <p>13 self-insured employer?</p> <p>14 A. There could be.</p> <p>15 Q. What are some of the ways in which they could</p> <p>16 differ?</p> <p>17 A. Could you be more specific?</p> <p>18 Q. You said there could be differences, so I'm just</p> <p>19 asking you to elaborate on that.</p> <p>20 What are some of the differences that could</p> <p>21 exist?</p> <p>22 A. Third-party payers are responsible for the</p> <p>23 management and reimbursement of the healthcare claims,</p> <p>24 including the prescription benefit. Self-insured employers</p> <p>25 would also be responsible in that same capacity but within</p>	<p style="text-align: right;">Page 41</p> <p>1 A. Yes.</p> <p>2 Q. Okay. What is the nature of your work with TPPs?</p> <p>3 A. The nature of my work in my role or as a pharmacy</p> <p>4 benefit consultant -- consultant is to advise on the</p> <p>5 benefits in all aspects, including formulary, design, and</p> <p>6 formulary ongoing management, utilization management</p> <p>7 programs, plan design updates, and -- and all functions</p> <p>8 related to the pharmacy benefit program.</p> <p>9 Q. Do you have any experience with P&T committees?</p> <p>10 A. I do.</p> <p>11 Q. What is the nature of your experience with P&T</p> <p>12 committees?</p> <p>13 A. Throughout my -- my career as a pharmacist, being</p> <p>14 intimately familiar with P&T committees is -- and</p> <p>15 understanding what their function is, has been integral in</p> <p>16 all aspects of my career.</p> <p>17 I have reviewed countless minutes from P&T</p> <p>18 committees. I do that on an ongoing basis to keep track</p> <p>19 of, if you will, what the progress is and what the</p> <p>20 functions and what -- the ongoing developments of the P&T</p> <p>21 committee, and so I'm -- you know, I'm very familiar with</p> <p>22 what they do and I have, you know, visibility into the P&T</p> <p>23 committees with whom my clients are engaged with, are</p> <p>24 involved with.</p> <p>25 Q. How do you obtain these minutes from P&T</p>

<p style="text-align: right;">Page 42</p> <p>1 committees?</p> <p>2 A. I request them.</p> <p>3 Q. From whom?</p> <p>4 A. Whomever the P&T committee is with.</p> <p>5 Q. And what -- what entities have you requested P&T</p> <p>6 committee's minutes from?</p> <p>7 A. PBMs and health plans.</p> <p>8 Q. Which specific ones?</p> <p>9 A. That's confidential information.</p> <p>10 Q. Why is that confidential information?</p> <p>11 A. It's tied into the clients that I provide</p> <p>12 counseling -- consulting for.</p> <p>13 Q. In connection with which company or which of your</p> <p>14 roles?</p> <p>15 A. My current role at ARMSRx.</p> <p>16 Q. Only at ARMSRx?</p> <p>17 A. Yes.</p> <p>18 Q. Have you ever been a TPP employee?</p> <p>19 A. No.</p> <p>20 Q. Have you ever been a member of a P&T committee?</p> <p>21 A. No.</p> <p>22 Q. Do you consider MSP to be a TPP committee?</p> <p>23 A. No.</p> <p>24 Q. And is it possible sometimes for both a TPA and a</p> <p>25 TPP to be involved in processing a particular claim?</p>	<p style="text-align: right;">Page 44</p> <p>1 A. No.</p> <p>2 Q. Which would be listed?</p> <p>3 A. Standard industry claims data for prescriptions</p> <p>4 would list the client as part of, you know, the fields, the</p> <p>5 client -- whoever the client is.</p> <p>6 Q. And would the client -- am I understanding</p> <p>7 correctly that the client would be either the TPA or the</p> <p>8 TPP?</p> <p>9 A. If you're asking with regards to claims data, the</p> <p>10 information within the industry claims data extract would</p> <p>11 include the client that is have -- that is receiving the</p> <p>12 prescription benefit. So it's tied directly into the</p> <p>13 client, whoever that entity is.</p> <p>14 Q. Okay. So it may not be possible from that</p> <p>15 information alone to tell whether the third party in each</p> <p>16 claim is a TPP or a TPA?</p> <p>17 A. From that data alone, no.</p> <p>18 Q. Okay. Dr. Panagos, you also list on your CV</p> <p>19 certain professional organizations that you're a member of,</p> <p>20 is that right?</p> <p>21 A. Yes.</p> <p>22 Q. You're a member of the American College of</p> <p>23 Healthcare Executives?</p> <p>24 A. Yes.</p> <p>25 Q. When did you first become a member?</p>
<p style="text-align: right;">Page 43</p> <p>1 MR. WHARTON: Can I hear that question again,</p> <p>2 please?</p> <p>3 MS. ISIDRO: Can you read it back, please?</p> <p>4 (The requested portion was read back.)</p> <p>5 A. TPAs manage the claims. They are not processing</p> <p>6 claims.</p> <p>7 BY MS. ISIDRO:</p> <p>8 Q. Who -- who does the pharmacy expect payment from</p> <p>9 among a TPA or a TPP?</p> <p>10 A. It depends on the structure of the arrangement</p> <p>11 and who's ultimately -- oh -- responsible for the payments.</p> <p>12 Q. So sometimes the pharmacy might expect payment</p> <p>13 from the TPA first, right?</p> <p>14 A. Could you be more specific?</p> <p>15 Q. You mentioned it depends on the structure of the</p> <p>16 particular arrangement, correct?</p> <p>17 A. Correct.</p> <p>18 Q. Are there sometimes arrangements where the</p> <p>19 pharmacy might expect payment from the TPA first?</p> <p>20 A. That wasn't the focus of my opinion that I'm</p> <p>21 rendering here today, but to answer the question, it could</p> <p>22 be.</p> <p>23 Q. In your experience with claim adjudication</p> <p>24 platforms, would both the TPA and the TPP be listed in the</p> <p>25 claims data?</p>	<p style="text-align: right;">Page 45</p> <p>1 A. 2019.</p> <p>2 Q. And you're still a member currently?</p> <p>3 A. Yes.</p> <p>4 Q. What is required to become a member of that</p> <p>5 organization?</p> <p>6 A. The requirements are listed on the website.</p> <p>7 There are certain qualifications and criteria that you must</p> <p>8 meet, and I don't recall them all at this moment.</p> <p>9 Q. Okay. Do you --</p> <p>10 A. But they are listed there.</p> <p>11 Q. Do you recall any?</p> <p>12 A. Must be a pharmacist in good standing or a</p> <p>13 healthcare professional in good standing.</p> <p>14 Q. Okay.</p> <p>15 A. Uh-huh.</p> <p>16 Q. And you're also a member of the Academy of</p> <p>17 Managed Care Pharmacy; is that right?</p> <p>18 A. Yes.</p> <p>19 Q. When did you become a member of that</p> <p>20 organization?</p> <p>21 A. When I was in pharmacy school.</p> <p>22 Q. And you're still a member currently?</p> <p>23 A. Yes.</p> <p>24 Q. What is required to become a member of that</p> <p>25 organization?</p>

<p style="text-align: right;">Page 46</p> <p>1 A. Again, those requirements are listed on the</p> <p>2 website and they -- it's a professional license or</p> <p>3 non- -- non-licensed individuals listed on the website.</p> <p>4 Q. Okay. You're a member of Women Leading</p> <p>5 Healthcare; is that right?</p> <p>6 A. Yes.</p> <p>7 Q. When did you become a member of that</p> <p>8 organization?</p> <p>9 A. 2020. Yeah. More recent.</p> <p>10 Q. And what is required to become a member of Women</p> <p>11 Leading Healthcare?</p> <p>12 A. Yes. That requires an appointment. You have to</p> <p>13 be invited to join by a current member.</p> <p>14 Q. And whom were you invited by?</p> <p>15 A. I was invited by a colleague who worked with me</p> <p>16 at the time.</p> <p>17 Q. Worked with you at which of your --</p> <p>18 A. At ARMSRx.</p> <p>19 Q. You're also a member of Healthcare</p> <p>20 Businesswomen's Association?</p> <p>21 A. Yes.</p> <p>22 Q. When did you become a member?</p> <p>23 A. I don't remember exactly the year.</p> <p>24 Q. Do you remember approximately?</p> <p>25 A. Maybe 2019, around that time.</p>	<p style="text-align: right;">Page 48</p> <p>1 pharmacy school.</p> <p>2 Q. Okay. And you're still a member today?</p> <p>3 A. Correct.</p> <p>4 Q. What is required to become a member of that</p> <p>5 organization?</p> <p>6 A. It's listed on the site. A professional licensed</p> <p>7 or non-licensed individuals may join and they -- a</p> <p>8 pharmacist in good standing.</p> <p>9 Q. Are you a member of any other professional</p> <p>10 organization besides the ones we've just discussed?</p> <p>11 A. No.</p> <p>12 Q. During your professional career, have you been a</p> <p>13 member of any other professional organization besides the</p> <p>14 ones we've just discussed?</p> <p>15 A. No.</p> <p>16 Q. Okay. And do you know whether there are any</p> <p>17 protocols, standards, or guidelines relating to the</p> <p>18 practice of pharmacy that are promulgated by any of these</p> <p>19 professional organizations?</p> <p>20 A. Would you please restate the question?</p> <p>21 Q. Sure. Why don't we start with the American</p> <p>22 College of Healthcare Executives. Does the American</p> <p>23 College of Healthcare Executives have any protocols,</p> <p>24 standards, or guidelines relating to the practice of</p> <p>25 pharmacy?</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. Okay.</p> <p>2 A. 2019.</p> <p>3 Q. So recently, in the last few years?</p> <p>4 A. Uh-huh.</p> <p>5 Q. Okay. What is required to become a member of</p> <p>6 Healthcare Businesswomen's Association?</p> <p>7 A. It would be -- again, it's listed on the website,</p> <p>8 all the criteria, but be in the healthcare field, be a</p> <p>9 woman in the healthcare field.</p> <p>10 Q. You're also a member of the American Association</p> <p>11 of Consultant Pharmacists?</p> <p>12 A. Correct.</p> <p>13 Q. When did you become a member?</p> <p>14 A. 2019 as well. 2018 perhaps. I don't remember</p> <p>15 exactly.</p> <p>16 Q. Okay. What is required to become a member of</p> <p>17 that organization?</p> <p>18 A. Again, those requirements are listed on the</p> <p>19 organization's site and among them include being a</p> <p>20 pharmacist in good standing.</p> <p>21 Q. And, finally, you're a member of the American</p> <p>22 Society of Health Systems Pharmacists?</p> <p>23 A. Correct.</p> <p>24 Q. When did you become a member?</p> <p>25 A. I initially became a member when I was in</p>	<p style="text-align: right;">Page 49</p> <p>1 A. No.</p> <p>2 Q. Does the Academy of Managed Care Pharmacy have</p> <p>3 any protocols, standards, or guidelines relating to the</p> <p>4 practice of pharmacy?</p> <p>5 A. Could you restate that question?</p> <p>6 Q. Do you know whether the Academy of Managed Care</p> <p>7 Pharmacy has any guidelines relating to the practice of</p> <p>8 pharmacy?</p> <p>9 A. Within the scope of managed care, they may</p> <p>10 provide recommendations or guidance.</p> <p>11 Q. Are there any that -- that you are personally</p> <p>12 aware of?</p> <p>13 A. As part of my role in my -- in my day-to-day</p> <p>14 functions, I review guidance and literature from these</p> <p>15 organizations and part of up -- keeping up with industry</p> <p>16 practice, and so it's always evolving, changing, and</p> <p>17 there's -- based on what's happening in the pharmacy</p> <p>18 practice and managed care world.</p> <p>19 Q. Does the Women Leading Healthcare organization</p> <p>20 issue any guidelines, protocols, or standards with respect</p> <p>21 to the practice of pharmacy?</p> <p>22 A. Not that I'm aware of.</p> <p>23 Q. How about the Healthcare Businesswomen's</p> <p>24 Association?</p> <p>25 A. Not that I am aware of.</p>

<p style="text-align: right;">Page 50</p> <p>1 Q. Does the American Association of Consultant 2 Pharmacists issue any guidelines relating to the practice 3 of pharmacy? 4 A. No, not guidelines. 5 Q. Any protocols relating to the practice of 6 pharmacy? 7 A. No. 8 Q. Any standards relating to the proto- -- to the 9 practice of pharmacy? 10 A. No. 11 Q. Does the American Association of Consultant 12 Pharmacists issue any sort of statements at all with 13 respect to the practice of pharmacy? 14 A. Yes. They provide information with regards to 15 consultant -- consulting pharmacy, yeah, so. 16 Q. What type of information? 17 A. Relevant to the field of consulting -- consultant 18 pharmacists, and that could be all -- anything related to 19 the pharmacy field. 20 Q. Is that in the nature of continuing education 21 information? 22 A. They do have continuing education, yes. 23 Q. What other types of information? 24 A. Industry information, clinical information as it 25 regards for consultant pharmacists. So anything tied into</p>	<p style="text-align: right;">Page 52</p> <p>1 research regarding nitrosamines? 2 A. No. 3 Q. Have you ever engaged in any professional 4 research regarding nitrosamines? 5 A. No. 6 Q. Have you ever published any articles relating to 7 nitrosamines? 8 A. No. 9 Q. Have you ever published any articles addressing 10 warranties? 11 A. No. 12 Q. Have you ever published any articles relating to 13 Valsartan or Valsartan-containing drugs? 14 A. No. 15 Q. Have you ever published any articles relating to 16 bioequivalence? 17 A. No. 18 Q. Have you ever published any articles relating to 19 the FDA regulatory requirements that apply to 20 pharmaceutical products? 21 A. No. 22 Q. Have you ever engaged in any academic or 23 professional research relating to Valsartan or 24 Valsartan-containing drugs? 25 MR. HANSEL: Object to the form.</p>
<p style="text-align: right;">Page 51</p> <p>1 the pharmacy practice before consulting is -- could be 2 on -- could be on their site or available. 3 Q. And does the American Society of Health System 4 Pharmacists issue any protocol, standards, or guidelines 5 relating to the practice of pharmacy? 6 A. Yes, they could. 7 Q. Are you personally aware of any protocols, 8 standards, or guidelines that they've issued with respect 9 to the practice of pharmacy? 10 A. They provide, you know, recommendations with 11 regards to health system pharmacists and function within 12 that capacity. 13 Q. Are you aware whether any of the professional 14 organizations that you're a member of issue any protocol, 15 standards, or guidelines with respect to litigation 16 consulting? 17 A. No. 18 Q. No you're not aware or you know that they don't? 19 A. No, I'm not aware. 20 Q. Okay. And do you know whether any of the 21 professional organizations that you're a member of issue 22 any protocols, standards, or guidelines with respect to 23 providing expert testimony? 24 A. No, I'm not aware. 25 Q. Okay. Have you ever engaged in any academic</p>	<p style="text-align: right;">Page 53</p> <p>1 A. Could you restate the question, please? 2 BY MS. ISIDRO: 3 Q. Sure. Have you ever engaged in any academic 4 research relating to Valsartan or Valsartan-containing 5 drugs? 6 MR. HANSEL: Object to the form. 7 A. No. 8 BY MS. ISIDRO: 9 Q. Have you ever engaged in any professional 10 research relating to Valsartan or Valsartan-containing 11 drugs? 12 MR. HANSEL: Object to the form. 13 A. Could you be more specific? 14 BY MS. ISIDRO: 15 Q. Have you ever researched Valsartan in connection 16 with your professional responsibilities? 17 A. Yes. 18 Q. In what context? 19 A. Again, I, in my role as a clinical pharmacist and 20 consultant, I am staying, you know, up to date with all 21 clinical information, pharmacy updates, medication updates, 22 new to drug -- new to market generic brands, generic 23 specialty, and so it -- I am knowledgeable on the drug. 24 Q. So when you say you're knowledgeable on the drug, 25 what are you referring to?</p>

<p style="text-align: right;">Page 54</p> <p>1 A. I understand what its intended use is for, what 2 category, therapeutic category it's in, the -- its 3 current -- its standing for inclusion in a formulary, and 4 all components, you know, related to the medication in 5 terms of formulary placement. 6 Q. Anything else? 7 MR. HANSEL: Object to the form. 8 A. Could you be more specific? 9 BY MS. ISIDRO: 10 Q. Have you conducted any research in Valsartan 11 other -- on Valsartan other than the categories that you 12 just mentioned? 13 A. No. 14 Q. Have you ever engaged in any academic or 15 professional research regarding bioequivalence? 16 MR. HANSEL: Object to the form. 17 A. My education and my experience are -- involve 18 those -- aspects of bioequivalence, and those are part of 19 the components. 20 BY MS. ISIDRO: 21 Q. Sorry, part of the components of your 22 education? 23 A. It's part of the curriculum in some way -- 24 throughout the pharmacy program. So it is -- it's not 25 unfamiliar to me.</p>	<p style="text-align: right;">Page 56</p> <p>1 BY MS. ISIDRO: 2 Q. As you sit here today, can you recall whether any 3 of those requirements including a course specifically on 4 bioequivalence? 5 MR. HANSEL: Object to the form. 6 A. No. 7 BY MS. ISIDRO: 8 Q. Have you ever authored any publications relating 9 to epidemiology? 10 A. No. 11 Q. Have you published any -- withdrawn. Let me 12 rephrase that. 13 Have you authored any publications in the last 14 ten years? 15 A. No. 16 Q. Have you ever authored any publications? 17 A. No. 18 Q. Have you ever given any presentations relating to 19 nitrosamines? 20 A. No. 21 Q. Have you ever given any presentations relating to 22 product warranties? 23 MR. HANSEL: Object to the form. 24 A. I advise my clients on drugs standing -- approval 25 standing, standing, and with regards to helping them with</p>
<p style="text-align: right;">Page 55</p> <p>1 Q. Did you take any courses on bioequivalence during 2 your pharmacy education? 3 A. Bioequivalence was incorporated into many courses 4 within the pharmacy program as it relates to the 5 medications we were studying at the time. 6 Q. So bioequivalence -- bioequivalence is a concept 7 that you're familiar with from your education as a 8 pharmacist, but you haven't taken any courses specifically 9 on bioequivalence; is that correct? 10 MR. HANSEL: Object to the form. 11 A. The -- I completed all the coursework required 12 for pharm- -- the pharmacy degree, both the bachelor's 13 degree and the doctor of pharmacy degree and fulfilled all 14 the requirements that those entail. 15 BY MS. ISIDRO: 16 Q. As you sit here today, you can't specifically 17 recall whether that entailed a course specifically on 18 bioequivalence? 19 MR. HANSEL: Object to the form. 20 A. Again, I completed all of the coursework required 21 for a pharmacy degree and I fulfilled all the requirements 22 for both bachelor's and doctorate of pharmacy degree, 23 including licensure in the State of New York that -- I 24 sufficed all of the academic requirements for all the 25 classwork.</p>	<p style="text-align: right;">Page 57</p> <p>1 the formulary. 2 BY MS. ISIDRO: 3 Q. And how does that relate to product warranties? 4 A. That the drug is in good standing and meets the 5 criteria for approval approved by the FDA. 6 Q. So you've never given a presentation, the focus 7 of which is product warranties? 8 MR. HANSEL: Object to the form. 9 A. My professional capacity includes advising my 10 clients and providing them guidance on -- on various drug 11 products, structure of their prescription benefit program, 12 and approvals and drugs in good standing for consideration 13 on the formulary. 14 BY MS. ISIDRO: 15 Q. Okay. I'm not asking you though about your 16 responsibilities in your client work. I'm asking about 17 whether you have ever given a verbal presentation to a 18 group of people with a topic focus on product warranties. 19 MR. HANSEL: Object to the form. 20 A. I have given a -- I have spoken to groups of 21 people with regards to the promises that a -- a drug is 22 listed to have or the approval that it has. 23 BY MS. ISIDRO: 24 Q. How many times have you given that presentation? 25 A. Many.</p>

<p style="text-align: right;">Page 58</p> <p>1 Q. To whom?</p> <p>2 A. To my clients.</p> <p>3 Q. Your clients in connection with which of your</p> <p>4 jobs?</p> <p>5 A. All of them.</p> <p>6 Q. And do you have Power Points that you use for</p> <p>7 those presentations?</p> <p>8 A. I have used Power Points.</p> <p>9 Q. Do you keep those Power Points?</p> <p>10 A. I share those with the clients.</p> <p>11 Q. What have the titles of those presentations been?</p> <p>12 A. Those are specific to the client and tied into</p> <p>13 their prescription benefit program.</p> <p>14 Q. And has any of those presentations been</p> <p>15 specifically focused on the topic of product warranties?</p> <p>16 MR. HANSEL: Object to the form.</p> <p>17 A. Product warranties are the promises that products</p> <p>18 make for consideration for inclusion on the pharmacy</p> <p>19 formulary is a component of that discussion.</p> <p>20 BY MS. ISIDRO:</p> <p>21 Q. What do you understand by the term product</p> <p>22 warranties?</p> <p>23 A. Product warranty is the promise that that product</p> <p>24 makes that it is safe and effective and meets the criteria</p> <p>25 for approval, as established by the FDA.</p>	<p style="text-align: right;">Page 60</p> <p>1 A. I have given presentations on drug products that</p> <p>2 are approved for use by the FDA.</p> <p>3 MS. ISIDRO: Sorry, can you read back my</p> <p>4 question, please?</p> <p>5 (The requested portion was read back.)</p> <p>6 MR. HANSEL: I object to the form of the</p> <p>7 question. Calls for a legal conclusion; asked and</p> <p>8 answered.</p> <p>9 A. I have given presentations with regard to</p> <p>10 approved drug products for consideration on product</p> <p>11 formularies, pharmacy benefit programs.</p> <p>12 BY MS. ISIDRO:</p> <p>13 Q. So is that a no, outside of your client work</p> <p>14 you've never given formal presentations on product</p> <p>15 warranties?</p> <p>16 MR. HANSEL: Object to the form.</p> <p>17 A. I have spoken about drug products that are</p> <p>18 approved for use to individuals and groups outside of my</p> <p>19 client base as well.</p> <p>20 BY MS. ISIDRO:</p> <p>21 Q. And to whom have you given those presentations?</p> <p>22 A. My patient to patient interactions, as well as my</p> <p>23 academic work with students.</p> <p>24 Q. So you consider your patient to patient</p> <p>25 interactions to be formal presentations?</p>
<p style="text-align: right;">Page 59</p> <p>1 Q. What is the basis of your understanding as to the</p> <p>2 meaning of the term product warranties?</p> <p>3 A. The basis of my understanding pulls in my many</p> <p>4 years of education, my many years of experience in the</p> <p>5 pharmacy roles that I've held, and my many years of</p> <p>6 experience in my consulting role, providing guidance to</p> <p>7 clients about their prescription benefit program and all</p> <p>8 aspects related to that.</p> <p>9 Q. Is it based on anything else or have we just</p> <p>10 fully discussed your basis for your understanding of that</p> <p>11 term?</p> <p>12 A. I've provided you the basis for that.</p> <p>13 THE WITNESS: May I take a break?</p> <p>14 MR. HANSEL: Yes.</p> <p>15 MS. ISIDRO: Sure.</p> <p>16 THE WITNESS: Thank you.</p> <p>17 THE VIDEOGRAPHER: The time is 10:49 a.m., and</p> <p>18 we're going off record.</p> <p>19 (Break taken.)</p> <p>20 THE VIDEOGRAPHER: The time is 11:08 a.m., and</p> <p>21 we're back on the record.</p> <p>22 BY MS. ISIDRO:</p> <p>23 Q. Dr. Panagos, outside of your client work, have</p> <p>24 you ever given any formal presentations on product</p> <p>25 warranties?</p>	<p style="text-align: right;">Page 61</p> <p>1 A. The patient to patient ones are -- the one on one</p> <p>2 ones are not formal.</p> <p>3 Q. Are you --</p> <p>4 A. But they are a presentation to the patient about</p> <p>5 their drug.</p> <p>6 Q. So when you refer to your patient to patient</p> <p>7 interactions, are you referring to any that are not one on</p> <p>8 one?</p> <p>9 A. In that respect it would be members that are part</p> <p>10 of my client base. So it could be more than one.</p> <p>11 Q. Sorry. We were talking about outside of your</p> <p>12 client base?</p> <p>13 MR. HANSEL: Object to the form.</p> <p>14 BY MS. ISIDRO:</p> <p>15 Q. Isn't that right?</p> <p>16 MR. HANSEL: Object to the form.</p> <p>17 A. When consulting a patient regarding their</p> <p>18 medication it is pharmacist to patient.</p> <p>19 BY MS. ISIDRO:</p> <p>20 Q. Okay. And that's one on one?</p> <p>21 A. Yes.</p> <p>22 Q. Other than that, can you think of any formal</p> <p>23 presentations that you've given outside of your client work</p> <p>24 relating to -- to product warranties?</p> <p>25 MR. HANSEL: Object to the form.</p>

<p style="text-align: right;">Page 62</p> <p>1 A. The presentations that I have done are listed in</p> <p>2 my CV and what I've expressed to you just now.</p> <p>3 BY MS. ISIDRO:</p> <p>4 Q. Okay. So if it's not listed in your CV, you</p> <p>5 haven't given a formal presentation on it?</p> <p>6 MR. HANSEL: Objection. That's not what she just</p> <p>7 said.</p> <p>8 MS. ISIDRO: Can you read back the last response,</p> <p>9 please?</p> <p>10 (The requested portion was read back.)</p> <p>11 BY MS. ISIDRO:</p> <p>12 Q. So am I understanding correctly that you have not</p> <p>13 given any formal presentations outside of what is listed in</p> <p>14 your CV?</p> <p>15 MR. HANSEL: Object to the form.</p> <p>16 A. No, that's not what I said. I said what is</p> <p>17 listed in my CV and what I have just expressed to you in</p> <p>18 terms of presentations to my clients regarding their drug</p> <p>19 product or prescription benefit program.</p> <p>20 BY MS. ISIDRO:</p> <p>21 Q. Okay. And outside of those two categories, there</p> <p>22 aren't any other formal presentations that you've given?</p> <p>23 MR. HANSEL: Object to the form.</p> <p>24 A. Formal presentations may include the work I did</p> <p>25 in academia with my students regarding drug products that</p>	<p style="text-align: right;">Page 64</p> <p>1 the courses that fall under that division so.</p> <p>2 Q. And what were the titles of you -- of the courses</p> <p>3 that you taught in that role?</p> <p>4 A. I cannot recall at this time.</p> <p>5 Q. Is there anywhere that you would be able to find</p> <p>6 that information?</p> <p>7 A. Yes.</p> <p>8 Q. Where?</p> <p>9 A. In the records during my time there. It's</p> <p>10 information that I've had -- I had with respect to the</p> <p>11 courses.</p> <p>12 Q. You say records of your time there. Are you</p> <p>13 referring to your personal records or the organization's</p> <p>14 records?</p> <p>15 A. They would be in both.</p> <p>16 Q. Now, looking at Page 3 of your CV, under</p> <p>17 communication, you state that you were a presenter PBMI</p> <p>18 Opioid epidemic, Health Underwriters organizations?</p> <p>19 A. Correct.</p> <p>20 Q. Can you describe what that refers to?</p> <p>21 A. PBI (sic) is the Pharmacy Benefit Management</p> <p>22 Institute and they hold webinars of -- related to the</p> <p>23 profession and I was a presenter along with my colleague at</p> <p>24 the time for a presentation on the Opioid epidemic.</p> <p>25 Q. When was that presentation?</p>
<p style="text-align: right;">Page 63</p> <p>1 are approved.</p> <p>2 BY MS. ISIDRO:</p> <p>3 Q. Have you ever taught a course relating to --</p> <p>4 withdrawn.</p> <p>5 What are the titles of the courses you've taught?</p> <p>6 A. One of the --</p> <p>7 MR. HANSEL: Objection: Asked and answered.</p> <p>8 A. Pharmacy orientation is one course.</p> <p>9 BY MS. ISIDRO:</p> <p>10 Q. Any others?</p> <p>11 A. The others were recitation courses and the</p> <p>12 department of social sciences and administrative services</p> <p>13 within the pharmacy program.</p> <p>14 Q. What were the titles of those courses?</p> <p>15 A. Those are listed in my CV.</p> <p>16 Q. Can -- on which page?</p> <p>17 A. Page 2.</p> <p>18 Q. Can you show me where it lists the titles of the</p> <p>19 courses?</p> <p>20 A. It lists that I was an adjunct assistant</p> <p>21 professor of pharmacy in the division of social and</p> <p>22 administrative sciences.</p> <p>23 Q. So it doesn't list the titles of the courses that</p> <p>24 you taught in that role?</p> <p>25 A. Correct. Those were recitation courses tied into</p>	<p style="text-align: right;">Page 65</p> <p>1 A. 2016.</p> <p>2 Q. Do you still have the materials from that</p> <p>3 presentation?</p> <p>4 A. No, I do not.</p> <p>5 Q. Were you paid to give that presentation?</p> <p>6 A. No, I was not.</p> <p>7 Q. And was that presentation via webinar you said?</p> <p>8 A. Yes.</p> <p>9 Q. Do you know how many people attended that</p> <p>10 presentation?</p> <p>11 A. No.</p> <p>12 Q. Other than your pharmacy license in New York, do</p> <p>13 you hold any other professional licenses?</p> <p>14 A. No.</p> <p>15 Q. Have you ever had your license suspended?</p> <p>16 A. No.</p> <p>17 Q. Have you ever been punished or sanctioned in any</p> <p>18 way by a professional board?</p> <p>19 A. No.</p> <p>20 Q. Have you ever worked or consulted with FDA?</p> <p>21 A. No.</p> <p>22 Q. Do you hold yourself out as an FDA regulatory</p> <p>23 expert?</p> <p>24 MR. HANSEL: Object to the form of the question.</p> <p>25 A. I hold myself as an expert on what the FDA has</p>

<p style="text-align: right;">Page 66</p> <p>1 approved for drug products, both brand and generics.</p> <p>2 BY MS. ISIDRO:</p> <p>3 Q. Do you hold yourself out as an expert on the</p> <p>4 process for approval of pharmaceutical products by the FDA?</p> <p>5 MR. HANSEL: Object to the form.</p> <p>6 A. I understand what the process entails by the FDA.</p> <p>7 BY MS. ISIDRO:</p> <p>8 Q. That wasn't my question. My question was do you</p> <p>9 hold yourself out as an expert on the process for approval</p> <p>10 of pharmaceutical products by the FDA?</p> <p>11 MR. HANSEL: Objection.</p> <p>12 A. Could you be more specific?</p> <p>13 MR. HANSEL: Excuse me. Asked and answered and</p> <p>14 that's -- that's getting into a little bit of</p> <p>15 harassment territory. She answered the question.</p> <p>16 MS. ISIDRO: I take issue with your</p> <p>17 characterization of that question as harassing. The</p> <p>18 witness is consistently failing to answer the question</p> <p>19 that is asked. This deposition is going to go for a</p> <p>20 really long time if that continues.</p> <p>21 The witness is being asked a question. If she</p> <p>22 doesn't understand the question, she can let me know</p> <p>23 that she doesn't understand the question, but,</p> <p>24 otherwise, I expect the witness to answer the question</p> <p>25 that's been asked.</p>	<p style="text-align: right;">Page 68</p> <p>1 (The requested portion was read back.)</p> <p>2 BY MS. ISIDRO:</p> <p>3 Q. Dr. Panagos, are you offering any expert opinions</p> <p>4 in this litigation on the process for approval of</p> <p>5 pharmaceutical products by the FDA?</p> <p>6 A. The process by -- for approval is established by</p> <p>7 the FDA --</p> <p>8 Q. Doctor, I'm going to stop you right there.</p> <p>9 MR. HANSEL: Excuse me. Let her finish her</p> <p>10 answer.</p> <p>11 BY MS. ISIDRO:</p> <p>12 Q. I'm asking you yes or no questions --</p> <p>13 MR. HANSEL: Objection. No. You just</p> <p>14 interrupted the witness. That's unacceptable.</p> <p>15 MS. ISIDRO: I am asking yes or no questions.</p> <p>16 You're making speaking objections, which are</p> <p>17 unacceptable.</p> <p>18 MR. HONIK: Let's go off the record. This is</p> <p>19 Ruben Honik. Is the court reporter taking down my</p> <p>20 comment?</p> <p>21 THE VIDEOGRAPHER: The time is 11:24. We're</p> <p>22 going off record.</p> <p>23 (Off the record.)</p> <p>24 MR. HANSEL: This is Greg Hansel. We're going</p> <p>25 back on the stenographic record. We are on the record</p>
<p style="text-align: right;">Page 67</p> <p>1 Can you please read back the last question?</p> <p>2 MR. HANSEL: Please also read back the answer</p> <p>3 when you do that.</p> <p>4 (The requested portion was read back.)</p> <p>5 A. The process for drug approval varies between</p> <p>6 brand and generics and I have an understanding of the</p> <p>7 process for -- for both of those drugs to be approved.</p> <p>8 BY MS. ISIDRO:</p> <p>9 Q. Is it your position that having an understanding</p> <p>10 of the process is all that it takes to be an expert on that</p> <p>11 process?</p> <p>12 MR. HANSEL: Objection. Calls for a legal</p> <p>13 conclusion. Object to the form of the question.</p> <p>14 A. I have been asked here today to render an opinion</p> <p>15 on what TPPs rely on when TPPs rely on or -- or consult</p> <p>16 when they're making -- with respect -- specifically to</p> <p>17 generic drugs for formulary decisions, and specific to</p> <p>18 generic drugs, that process involves an approval by the FDA</p> <p>19 tied to an ANDA application whereby the manufacturer has to</p> <p>20 meet the criteria for approval in order for that generic</p> <p>21 drug to gain their approval. That's what I've been asked</p> <p>22 to render an opinion on.</p> <p>23 Was there something more you were looking for?</p> <p>24 MS. ISIDRO: Can you read back the question and</p> <p>25 the answer, please?</p>	<p style="text-align: right;">Page 69</p> <p>1 stenographically.</p> <p>2 On behalf of the Plaintiffs, we object pursuant</p> <p>3 to Federal Rule of Civil Procedure 30(d)(3), motion to</p> <p>4 terminate or limit which states in part: A, at any</p> <p>5 time during a deposition the deponent or a party may</p> <p>6 move to terminate or limit it on the ground that it is</p> <p>7 being conducted in bad faith or in a manner that</p> <p>8 unreasonably annoys, embarrasses, or oppresses the</p> <p>9 deponent or party.</p> <p>10 On behalf of the Plaintiffs, Defendants have</p> <p>11 questioned Dr. Panagos for over two hours or</p> <p>12 approximately two hours on qualifications only. In</p> <p>13 addition to that, Defense counsel has repeatedly</p> <p>14 re-asked the same question on numerous occasions, in</p> <p>15 particular a question about whether the witness is</p> <p>16 qualified as an expert witness under federal procedure</p> <p>17 in effect. That question is a legal conclusion, calls</p> <p>18 for a legal conclusion. It's a question for the</p> <p>19 Court.</p> <p>20 The witness is not an attorney. The witness does</p> <p>21 not know standards for acceptance of expert witnesses</p> <p>22 by federal courts under Daubert and other law. It is</p> <p>23 the parties, the Plaintiffs who have offered the</p> <p>24 expert, and even if the Defendants are not happy with</p> <p>25 the answer provided by the expert, that is not a</p>

<p style="text-align: right;">Page 70</p> <p>1 ground to badger the witness, to repeatedly ask the</p> <p>2 question calling for a legal conclusion, and, in</p> <p>3 effect, harassing Dr. Panagos.</p> <p>4 It's discourteous, it's not civil, and the</p> <p>5 Plaintiffs will not permit it to continue. We would</p> <p>6 like to request the Defendants for an offer of proof</p> <p>7 at this time of how much longer they intend to ask the</p> <p>8 witness about her qualifications and on which topics</p> <p>9 of her qualifications they intend to examine the</p> <p>10 witness.</p> <p>11 We will consider that, and if it is unacceptable</p> <p>12 under Rule 30(d)(3), we will terminate the portion of</p> <p>13 the examination on qualifications to the extent only</p> <p>14 that we believe it is impermissible.</p> <p>15 Is there anything else you'd like to add, Conlee,</p> <p>16 Charlie, Jorge?</p> <p>17 MS. WHITELEY: No.</p> <p>18 MR. HANSEL: Ruben? Anyone? Thank you.</p> <p>19 MR. KERNER: The only thing I'd like to say is I</p> <p>20 would like an opportunity to confer with Defense</p> <p>21 counsel.</p> <p>22 MR. HANSEL: Of course.</p> <p>23 MR. KERNER: So we're going to need a couple of</p> <p>24 minutes.</p> <p>25 MR. HANSEL: Sure. We'll step out.</p>	<p style="text-align: right;">Page 72</p> <p>1 this litigation. A yes or no question about whether</p> <p>2 she intended to offer specific opinions regarding the</p> <p>3 FDA process for drug approval in this litigation.</p> <p>4 So, with that in mind, I would suggest that we</p> <p>5 continue with the deposition at this time, and as long</p> <p>6 as the witness answers the questions that have been</p> <p>7 asked, bearing in mind that you have an opportunity to</p> <p>8 Redirect after Defendants have asked their</p> <p>9 questions -- and so as long as she answers the</p> <p>10 questions that have been asked, I don't see any reason</p> <p>11 why there should be any problem continuing with the</p> <p>12 deposition at this time.</p> <p>13 MS. WHITELEY: May I ask a question rather</p> <p>14 than -- do you have an amount of time that you have an</p> <p>15 idea of how long that you think it will continue on</p> <p>16 qualifications?</p> <p>17 MS. ISIDRO: It should not be much longer,</p> <p>18 assuming the witness does answer the questions that</p> <p>19 have been asked. But if the witness continues to be</p> <p>20 evasive and, you know, we continue to have to ask the</p> <p>21 question ten different ways so that the original</p> <p>22 question can be answered by the witness, then it -- it</p> <p>23 will need to go much -- it will need to go longer and</p> <p>24 it's not on me to -- it's not within my power to be</p> <p>25 able to determine that. It's -- it's much more within</p>
<p style="text-align: right;">Page 71</p> <p>1 MR. KERNER: Yeah. I'd appreciate that.</p> <p>2 (Break taken.)</p> <p>3 MR. KERNER: And so we will respond to your</p> <p>4 statements earlier.</p> <p>5 MS. ISIDRO: So, Counsel, I would like to state</p> <p>6 for the record that I categorically disagree with any</p> <p>7 suggestion that the questions that have been -- that</p> <p>8 have been asked here today are harassing or designed</p> <p>9 to embarrasses the witness in any way.</p> <p>10 Unfortunately, the witness has repeatedly</p> <p>11 answered the question that she has wanted to answer</p> <p>12 rather than the question that has been asked.</p> <p>13 In addition, there has been a pattern of speaking</p> <p>14 objections from Plaintiff's counsel, culminating in</p> <p>15 this inappropriate attempt to baselessly terminate or</p> <p>16 limit this deposition and to interfere with</p> <p>17 Defendant's rights to thoroughly explore the</p> <p>18 qualifications, as well as the -- the qualifications</p> <p>19 of the expert that Plaintiffs are offering, as well as</p> <p>20 the content and the bases for her opinions that she</p> <p>21 intends to offer in this litigation.</p> <p>22 I note that you threatened to suspend the</p> <p>23 deposition of the witness after she was asked not a</p> <p>24 question about her qualifications but a question about</p> <p>25 whether she intended to offer specific opinions in</p>	<p style="text-align: right;">Page 73</p> <p>1 the witness's power to determine how she's going to be</p> <p>2 answering questions.</p> <p>3 MR. KERNER: Anybody else on the Defense side</p> <p>4 have anything that they want to add?</p> <p>5 MR. GISLESON: Yeah. This is John Gisleson from</p> <p>6 Morgan Lewis on behalf of Aurobindo.</p> <p>7 We do not believe that the questioning has been</p> <p>8 in any way inappropriate. The tone has been fair and</p> <p>9 balanced, and in our view the witness has been</p> <p>10 nonresponsive and evasive.</p> <p>11 MR. KERNER: Anyone else on the Defense side?</p> <p>12 The only thing I'll add is our intention is to</p> <p>13 move forward efficiently, to continue to ask</p> <p>14 appropriate questions, to continue to ask</p> <p>15 professionally, as counsel's been doing all morning,</p> <p>16 and to treat the witness with respect, as counsel has</p> <p>17 done all morning, and move forward with the deposition</p> <p>18 and get through it as quickly as we can.</p> <p>19 There's no intent to keep this witness here one</p> <p>20 minute longer than necessary.</p> <p>21 MR. HANSEL: Anything else from the Defendants?</p> <p>22 MS. ISIDRO: Not at this time.</p> <p>23 MR. HANSEL: All right. On behalf of the</p> <p>24 Plaintiffs, we disagree with your statements that the</p> <p>25 witness has been nonresponsive or evasive and we stand</p>

<p style="text-align: right;">Page 74</p> <p>1 by our statements earlier, which I will not repeat.</p> <p>2 Based on your representations, particularly to</p> <p>3 Attorney Whiteley's questions, that you intend to</p> <p>4 reach a conclusion to the questioning about</p> <p>5 qualifications with reasonable efficiency, we will</p> <p>6 allow the questioning of Dr. Panagos to continue now,</p> <p>7 including to a limited extent on qualifications, and</p> <p>8 I -- I guess if there's one thing I want to reiterate,</p> <p>9 it's that she is not -- we're not holding her out as</p> <p>10 an expert on Daubert and on what Federal Court</p> <p>11 standards are for the acceptance of expert witnesses,</p> <p>12 which is a legal question for the Court.</p> <p>13 So, having said that, I will go get Dr. Panagos</p> <p>14 to -- to get started. Thank you.</p> <p>15 MS. ISIDRO: Thank you.</p> <p>16 (Off the record.)</p> <p>17 THE VIDEOGRAPHER: The time is 12:17 p.m., and we</p> <p>18 are back on record.</p> <p>19 BY MS. ISIDRO:</p> <p>20 Q. Dr. Panagos, are you intending to offer any</p> <p>21 opinions in this litigation on the process for obtaining</p> <p>22 approvals from FDA for pharmaceutical products?</p> <p>23 MR. HANSEL: Object to the form.</p> <p>24 A. The process has already been established by the</p> <p>25 FDA for approval of drugs.</p>	<p style="text-align: right;">Page 76</p> <p>1 MR. HANSEL: Object to the form.</p> <p>2 A. As a pharmacist, I understand the process</p> <p>3 involved for approval of generic drug products as it</p> <p>4 entails how those decisions are tied into a formulary</p> <p>5 placement.</p> <p>6 BY MS. ISIDRO:</p> <p>7 Q. And will you be offering expert opinions in this</p> <p>8 litigation involving that process?</p> <p>9 MR. HANSEL: Object to the form. Her report</p> <p>10 speaks for itself.</p> <p>11 A. My expert opinion is what TPPs rely on and</p> <p>12 consider with respect to generic drugs for placement to the</p> <p>13 drug formulary.</p> <p>14 BY MS. ISIDRO:</p> <p>15 Q. That is the only category of information on which</p> <p>16 you intend to offer expert opinions in this litigation?</p> <p>17 MR. HANSEL: Object to the form.</p> <p>18 A. My expert opinion is on what TPPs rely on when</p> <p>19 consideration -- for consideration of generic drugs as --</p> <p>20 for consideration to be placed on the formulary and it --</p> <p>21 reimburse as part of prescription drug program.</p> <p>22 BY MS. ISIDRO:</p> <p>23 Q. That is the only category on which you are -- you</p> <p>24 will be opining in this litigation?</p> <p>25 MR. HANSEL: I object to the form of the</p>
<p style="text-align: right;">Page 75</p> <p>1 Could you restate the question?</p> <p>2 BY MS. ISIDRO:</p> <p>3 Q. Are you intending to offer any opinions in this</p> <p>4 litigation on the process of obtaining approvals from FDA</p> <p>5 for generic pharmaceutical products?</p> <p>6 MR. HANSEL: Object to the form.</p> <p>7 A. I am rendering an opinion on what TPPs,</p> <p>8 third-party payers, rely on with respect to generic drugs</p> <p>9 for consideration to a drug formulary.</p> <p>10 BY MS. ISIDRO:</p> <p>11 Q. So you're not intending to offer any opinions on</p> <p>12 the process for obtaining approvals from FDA for generic</p> <p>13 pharmaceutical products?</p> <p>14 MR. HANSEL: Object to the form: Asked and</p> <p>15 answered, argumentative.</p> <p>16 A. The process for approval of generic drug products</p> <p>17 is already established by the FDA.</p> <p>18 BY MS. ISIDRO:</p> <p>19 Q. Would you defer to FDA on that process?</p> <p>20 MR. HANSEL: Object to the form.</p> <p>21 A. Would you please be more specific?</p> <p>22 BY MS. ISIDRO:</p> <p>23 Q. Would you defer to FDA with respect to matters</p> <p>24 involving the process for obtaining approvals for</p> <p>25 pharmaceutical products?</p>	<p style="text-align: right;">Page 77</p> <p>1 question.</p> <p>2 BY MS. ISIDRO:</p> <p>3 Q. You can answer.</p> <p>4 A. As I understand your question, that is what my</p> <p>5 opinion will be rendered upon.</p> <p>6 Q. Have you ever had any formal training in</p> <p>7 economics?</p> <p>8 A. What do you mean by formal? Could you define</p> <p>9 that?</p> <p>10 Q. Have you ever done any coursework in economics?</p> <p>11 A. As part of my college degrees, some of the</p> <p>12 coursework entailed economics.</p> <p>13 Q. Was that as part of one of your majors?</p> <p>14 A. Yes.</p> <p>15 Q. Which ones?</p> <p>16 A. Biology and as well as pharmacy.</p> <p>17 Q. Have you ever obtained any certifications in</p> <p>18 economics?</p> <p>19 A. No.</p> <p>20 Q. Have you ever obtained any degrees in economics?</p> <p>21 A. No.</p> <p>22 Q. Have you ever had any formal training in business</p> <p>23 principles?</p> <p>24 A. Business coursework was also part of my college</p> <p>25 education.</p>

<p style="text-align: right;">Page 78</p> <p>1 Q. In connection with which of your majors or</p> <p>2 minors?</p> <p>3 A. Both biology, computer science, and pharmacy. So</p> <p>4 all -- all -- both majors and the minor.</p> <p>5 Q. Outside of your college degrees, have you had any</p> <p>6 other coursework in business?</p> <p>7 A. Only as it pertains to my continuing education</p> <p>8 credits for upholding my pharmacy degree, so business</p> <p>9 related to pharmacy continuing education.</p> <p>10 Q. Have you received any certificates in business?</p> <p>11 A. No.</p> <p>12 Q. Have you received any degrees in business?</p> <p>13 A. No.</p> <p>14 Q. You are not a medical doctor, correct?</p> <p>15 A. No.</p> <p>16 Q. You're not a pharmacologist?</p> <p>17 A. No.</p> <p>18 Q. And you're not a toxicologist?</p> <p>19 A. No.</p> <p>20 Q. Aside from this litigation, have you ever been</p> <p>21 retained as an expert witness or an expert consultant in</p> <p>22 connection with litigation?</p> <p>23 A. No.</p> <p>24 Q. And you testified you've never been</p> <p>25 deposited before. Have you ever testified at trial</p>	<p style="text-align: right;">Page 80</p> <p>1 BY MS. ISIDRO:</p> <p>2 Q. If you'd like to refer back to them at any point,</p> <p>3 you're welcome to. I'm happy to take them back if it's too</p> <p>4 cluttered.</p> <p>5 A. It's okay.</p> <p>6 MR. HANSEL: Why don't you leave them nearby.</p> <p>7 THE WITNESS: I'm fine.</p> <p>8 MS. ISIDRO: Okay.</p> <p>9 THE WITNESS: I'm good. Thank you.</p> <p>10 BY MS. ISIDRO:</p> <p>11 Q. Okay. And you're I believe still on Page 6,</p> <p>12 correct?</p> <p>13 A. Correct. Uh-huh.</p> <p>14 Q. Okay. Item Number 2 asks for articles,</p> <p>15 abstracts, studies, reports, et cetera, and am I</p> <p>16 understanding your testimony correct, you don't have any</p> <p>17 items responsive to Number 2?</p> <p>18 MR. HANSEL: Excuse me. I'm going to object. I</p> <p>19 object to the form of the question because we've</p> <p>20 provided a written response as well.</p> <p>21 A. Everything is included in my expert report, in my</p> <p>22 CV. All the materials necessary for this expert opinion</p> <p>23 that I'm providing are within the report and my CV.</p> <p>24 BY MS. ISIDRO:</p> <p>25 Q. Okay. But, Doctor, you've never authored any</p>
<p style="text-align: right;">Page 79</p> <p>1 before?</p> <p>2 A. No.</p> <p>3 Q. Have you ever done consulting work for any</p> <p>4 pharmaceutical company?</p> <p>5 A. No.</p> <p>6 Q. Have you ever done consulting work for any</p> <p>7 medical device company?</p> <p>8 A. No.</p> <p>9 Q. What percent of your income is currently derived</p> <p>10 from expert testimony or expert consulting in connection</p> <p>11 with litigation?</p> <p>12 A. I have not calculated the percentage, but it's</p> <p>13 only with regards to the case I'm providing an expert</p> <p>14 report for here.</p> <p>15 Q. Okay. Doctor, if we could turn back to Exhibit</p> <p>16 1, which was your notice of deposition.</p> <p>17 A. Uh-huh.</p> <p>18 Q. You can pass Exhibit 2 back to me, just so you</p> <p>19 don't have too many papers in front of you.</p> <p>20 MR. HANSEL: She may want to refer to the other</p> <p>21 exhibits.</p> <p>22 MS. ISIDRO: Oh, certainly. If -- if you would</p> <p>23 like --</p> <p>24 MR. HANSEL: If she could keep them there, I</p> <p>25 would appreciate it.</p>	<p style="text-align: right;">Page 81</p> <p>1 articles, correct?</p> <p>2 A. Correct.</p> <p>3 MR. HANSEL: Object to the form.</p> <p>4 BY MS. ISIDRO:</p> <p>5 Q. And you've never authored or co-authored any</p> <p>6 abstracts, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And you've never authored or co-authored any</p> <p>9 published studies, correct?</p> <p>10 A. Correct.</p> <p>11 Q. You've never authored or co-authored any</p> <p>12 published reports, correct?</p> <p>13 A. Correct.</p> <p>14 Q. You've never authored or co-authored any</p> <p>15 publications, correct?</p> <p>16 A. Right.</p> <p>17 Q. Okay. You've never authored or co-authored any</p> <p>18 book chapters?</p> <p>19 A. No.</p> <p>20 Q. Or any books in their entirety, correct?</p> <p>21 A. That is correct.</p> <p>22 Q. Do you have in your possession, Doctor, any</p> <p>23 presentations -- withdrawn. Let me ask a different</p> <p>24 question.</p> <p>25 Have you ever given any presentations or speeches</p>

<p style="text-align: right;">Page 82</p> <p>1 regarding drug safety and cancer risk?</p> <p>2 A. That's a broad question but I have spoken about</p> <p>3 drug safety and the potential for side effects or adverse</p> <p>4 effects as related to that drug. Those can include cancer.</p> <p>5 Q. And in what context have -- have those speaking</p> <p>6 engagements been?</p> <p>7 A. In every context as my professional -- in my</p> <p>8 professional career as a pharmacist. So in my current</p> <p>9 role, in my academic role, and in my previous roles in</p> <p>10 my -- with my previous employment.</p> <p>11 Q. So has -- have those been specifically with and</p> <p>12 for your clients?</p> <p>13 MR. HANSEL: Object to the form.</p> <p>14 A. Primarily for my clients. But also for, if I was</p> <p>15 involved in a speaking engagement with my organization, it</p> <p>16 could have been to an audience that was not my client.</p> <p>17 BY MS. ISIDRO:</p> <p>18 Q. On how many occasions would you have spoken to an</p> <p>19 audience that went beyond your clients?</p> <p>20 A. A few times a year. A few times a year, once a</p> <p>21 quarter maybe.</p> <p>22 Q. During what time frame?</p> <p>23 A. Again, it's been throughout my career. So I've</p> <p>24 been doing this work here now for 20 plus years and so it's</p> <p>25 been throughout my career, sometimes more, sometimes less.</p>	<p style="text-align: right;">Page 84</p> <p>1 A. Right. That was not the focus of the</p> <p>2 presentation.</p> <p>3 Q. I understand you're saying it's not the focus and</p> <p>4 I just want to make sure that I'm understanding your</p> <p>5 answer.</p> <p>6 A. Uh-huh.</p> <p>7 Q. It was not the focus and you don't specifically</p> <p>8 recall discussing it, although it's possible you may have</p> <p>9 discussed it?</p> <p>10 MR. HANSEL: Objection. I object to the form.</p> <p>11 Asked and answered, repeatedly.</p> <p>12 BY MS. ISIDRO:</p> <p>13 Q. Is that --</p> <p>14 A. My --</p> <p>15 Q. -- is my understanding correct?</p> <p>16 A. My professional responsibility as a pharmacist</p> <p>17 when speaking about medications includes discussion of any</p> <p>18 potential concerns with the drug, including cancer, if it's</p> <p>19 relevant to the discussion. So I believe I'm answering</p> <p>20 your question.</p> <p>21 Q. Okay. So I'll take that to mean that my</p> <p>22 understanding is correct and you may have discussed it but</p> <p>23 you don't specifically recall discussing it.</p> <p>24 MR. HANSEL: Objection and move to strike.</p> <p>25 Object to the form.</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. What was most recent one?</p> <p>2 A. The most recent engagement was to the Chicago</p> <p>3 Healthcare Underwriters speaking about pharmacy benefit</p> <p>4 programs.</p> <p>5 Q. When was that?</p> <p>6 A. That was, goodness, before COVID. So I'm trying</p> <p>7 to think of the date. I can't recall the exact date, but</p> <p>8 it was before the -- the COVID lockdown.</p> <p>9 Q. Okay. And were you discussing cancer risk in</p> <p>10 connection with pharmaceutical products during that</p> <p>11 presentation?</p> <p>12 A. We were discussing pharmacy benefit information,</p> <p>13 drug safety, drug formulary plan designs.</p> <p>14 Q. So you don't specifically recall discussing</p> <p>15 cancer risk?</p> <p>16 A. It was not the focus of the presentation.</p> <p>17 Q. To the best of your recollection, was it</p> <p>18 discussed during the presentation?</p> <p>19 A. Again, it was not the focus, but whenever you</p> <p>20 talk about a drug, you bring in I guess a clinical</p> <p>21 pharmacist for the side effects or adverse effects or any</p> <p>22 concerns.</p> <p>23 Q. So it's possible that you may have discussed it,</p> <p>24 but you don't specifically recall discussing it; is that</p> <p>25 correct?</p>	<p style="text-align: right;">Page 85</p> <p>1 BY MS. ISIDRO:</p> <p>2 Q. And please feel free to correct me if I'm wrong</p> <p>3 in my interpretation.</p> <p>4 MR. HANSEL: Again, object to the form.</p> <p>5 BY MS. ISIDRO:</p> <p>6 Q. Am I correct that your -- that all of the</p> <p>7 materials that you have relied on in forming your opinions</p> <p>8 in this case have been listed in the attachments to -- to</p> <p>9 your report?</p> <p>10 A. All the materials have been listed, yes, in the</p> <p>11 attachment.</p> <p>12 Q. Okay. And let's go ahead and mark a copy of your</p> <p>13 report and its exhibits as Exhibit Number 3.</p> <p>14 MS. ISIDRO: She just needs to mark it first.</p> <p>15 Sorry.</p> <p>16 MR. HANSEL: Can I have a copy?</p> <p>17 MS. ISIDRO: Oh, I have it here. Sorry about</p> <p>18 that.</p> <p>19 MR. KERNER: Yeah.</p> <p>20 MR. HANSEL: I'm sorry.</p> <p>21 (Exhibit No. 3 was marked for identification.)</p> <p>22 BY MS. ISIDRO:</p> <p>23 Q. And, Doctor, if you could turn to exhibit --</p> <p>24 excuse me, Appendix A --</p> <p>25 A. Uh-huh.</p>

<p style="text-align: right;">Page 86</p> <p>1 Q. -- attached to your report. If you could just 2 take a moment to review that and confirm for me that that 3 is a complete list of the materials that you have relied on 4 in forming your opinions in connection with this 5 litigation. 6 A. This is a list of my materials that I've 7 reviewed. My expert opinion is based on my experience, my 8 education, my day-to-day upkeep of my profession to stay up 9 to date with what's happening, and -- and the materials 10 that I've reviewed are included here. 11 Q. Okay. And as far as the materials that you've 12 reviewed, Appendix B -- excuse me -- 13 A. A. 14 Q. -- Appendix A to your report is a complete list 15 of the materials you've reviewed in connection with this -- 16 with your opinions in this litigation? 17 MR. HANSEL: Object to the form. 18 A. My day-to-day responsibilities include reviewing 19 many pharmacy and industry articles, data, and information, 20 but with regards to this expert opinion the materials that 21 I reviewed are listed in Appendix A. 22 BY MS. ISIDRO: 23 Q. You haven't reviewed any medical records in 24 connection with this litigation, correct? 25 MR. HANSEL: Object to the form.</p>	<p style="text-align: right;">Page 88</p> <p>1 A. I mean, consumed is -- you've used the word 2 consumed. I'm not -- 3 Q. Doctor, have you been tracking your charges in 4 connection with this litigation? 5 A. Yes. I keep a record of my -- the time I spend 6 on this case. Absolutely. 7 Q. How do you track the time that you spend on this 8 case? 9 A. I keep a record of the time I spent in my own 10 personal file. 11 Q. Are they written notes? Do you use a program or 12 an app to track your time? How exactly do you keep those 13 records? 14 A. It's a combination of written and tracked through 15 an Excel. 16 Q. An Excel spreadsheet that -- that you populate? 17 A. That's correct. 18 Q. Okay. What is your hourly -- what is the hourly 19 rate at which you are being compensated in connection with 20 this litigation? 21 A. The hourly rate for non-testifying work is \$375 22 an hour and for testifying work it's \$400 an hour. 23 Q. What is your arrangement with respect to the 24 retainer? And I'll explain what I mean. Is it -- is it 25 something that's just there to guarantee payment or is it</p>
<p style="text-align: right;">Page 87</p> <p>1 A. Would you please be more specific than medical 2 records? 3 BY MS. ISIDRO: 4 Q. Have you -- I'll rephrase the question. 5 Have you reviewed any medical records pertaining 6 to the Plaintiffs in this litigation? 7 A. No. 8 Q. Have you spoken to any of the Plaintiffs in this 9 litigation? 10 A. No. 11 Q. Have you spoken to any of the other experts that 12 Plaintiffs have disclosed in this litigation? 13 A. No. 14 Q. Have you issued any invoices in connection with 15 your work in this litigation? 16 A. I will -- I have not issued any invoices, but I 17 did receive a retainer at the onset. 18 Q. And what was the amount of the retainer that you 19 received at -- at the outset? 20 A. \$4,500. 21 Q. Has that retainer been -- let me rephrase that. 22 Have -- have there been amounts consumed from 23 that retainer? 24 A. Are you asking if I've used the monies? 25 Q. No, Doctor.</p>	<p style="text-align: right;">Page 89</p> <p>1 something on which you collect your fees as they are 2 incurred up to the extent of the retainer or a different 3 arrangement with respect to the retainer? 4 A. The retainer was for my expert report. 5 Q. Okay. And have you calculated the total amount 6 of fees that you have incurred based on your time spent 7 and -- and your hourly rate, up until today? 8 A. I have kept a report of the time I've spent for 9 this expert report and case and I have that -- I have that 10 recordkeeping, if you will. 11 Q. What is the total number of non-testifying hours 12 that you have spent to date on this litigation? 13 A. Approximately 50 to 60 hours. 14 Q. I'm sorry? I didn't hear you. 15 A. Fifty to -- about approximately fifty hours. 16 Q. Approximately 50 hours. So at your 17 non-testifying rate of \$375 an hour, that would be 18 approximately \$18,750 in fees in connection with your 19 non-testifying work so far; is that right? 20 A. You calculated it so. 21 Q. So that exceeds the amount of -- of the retainer, 22 correct? 23 A. Yes. 24 Q. Will that retainer remain in place and you will 25 invoice Plaintiffs for the full amount of -- of the fees</p>

<p style="text-align: right;">Page 90</p> <p>1 that you have incurred so far, or will you reduce the</p> <p>2 amount that you invoice by the amount of the retainer?</p> <p>3 A. I will reduce it by the amount of the retainer.</p> <p>4 Q. Okay. When were you first retained in connection</p> <p>5 with this litigation?</p> <p>6 A. The exact date I'm -- I have to look at the exact</p> <p>7 date, but it was in October I want to say or maybe late</p> <p>8 September of '21.</p> <p>9 Q. Who first contacted you in connection with this</p> <p>10 litigation?</p> <p>11 A. Greg Hansel.</p> <p>12 Q. Did you know Greg Hansel before he contacted you</p> <p>13 in connection with this litigation?</p> <p>14 A. No.</p> <p>15 Q. Do you know how you came to be contacted in</p> <p>16 connection with this litigation?</p> <p>17 A. I was told it was through my LinkedIn profile.</p> <p>18 Q. When you do issue an invoice in connection with</p> <p>19 your work in this litigation, who will you be sending that</p> <p>20 invoice to?</p> <p>21 A. Preti Flaherty.</p> <p>22 Q. I'm going to go ahead and mark this document as</p> <p>23 Exhibit 4.</p> <p>24 (Exhibit No. 4 was marked for identification.)</p> <p>25 Do you recognize this document, Doctor?</p>	<p style="text-align: right;">Page 92</p> <p>1 claims at issue in the litigation?</p> <p>2 A. No.</p> <p>3 Q. Has anyone assisted you in doing research or</p> <p>4 gathering information in connection with the opinions that</p> <p>5 you're offering in this litigation?</p> <p>6 A. No.</p> <p>7 Q. What were you asked to do when you were retained</p> <p>8 in connection with this litigation?</p> <p>9 A. I would ask -- I was asked to render an opinion</p> <p>10 on what TPPs rely on when -- with respect to generic</p> <p>11 medications.</p> <p>12 Q. Other than Plaintiff's counsel, have you spoken</p> <p>13 to anyone about this litigation?</p> <p>14 A. No.</p> <p>15 MS. ISIDRO: Counsel, I'm about to start getting</p> <p>16 into Dr. Panagos's report. Should we break for lunch</p> <p>17 at this time and -- and then come back or should we</p> <p>18 get started and break at a later time?</p> <p>19 MR. HANSEL: Let's break.</p> <p>20 MS. ISIDRO: Okay.</p> <p>21 MR. KERNER: How long? What do you think?</p> <p>22 THE VIDEOGRAPHER: The time is 12:53 p.m., and we</p> <p>23 are off record.</p> <p>24 (Break taken.)</p> <p>25 THE VIDEOGRAPHER: The time is 1:56 p.m., and we</p>
<p style="text-align: right;">Page 91</p> <p>1 A. Yes.</p> <p>2 Q. And what is it?</p> <p>3 A. It is the engagement letter.</p> <p>4 Q. Your engagement letter in connection with this</p> <p>5 litigation?</p> <p>6 A. Yes.</p> <p>7 Q. All right. What materials did you initially</p> <p>8 review in connection with this litigation?</p> <p>9 A. All of the materials I reviewed are in the</p> <p>10 appendix.</p> <p>11 Q. Let me ask my question a different way.</p> <p>12 Did you review any materials prior to making a</p> <p>13 determination as to whether or not you would agree to your</p> <p>14 engagement in connection with this litigation?</p> <p>15 A. So, again, my day-to-day functions in my</p> <p>16 professional role include reviewing pharmacy literature and</p> <p>17 materials, industry relevant information so that I am aware</p> <p>18 of -- so I can best advise my clients in -- in my</p> <p>19 professional capacity so.</p> <p>20 Q. In making a decision as to whether or not you</p> <p>21 would agree to be engaged in connection with this</p> <p>22 litigation, did you review any materials relating to the</p> <p>23 litigation itself?</p> <p>24 A. No.</p> <p>25 Q. Did you review any materials relating to the</p>	<p style="text-align: right;">Page 93</p> <p>1 are back on the record.</p> <p>2 BY MS. ISIDRO:</p> <p>3 Q. Good afternoon, Dr. Panagos. Do you still have</p> <p>4 in front of you Exhibit Number 3, your report with its</p> <p>5 Appendixes?</p> <p>6 A. I do.</p> <p>7 Q. All right. We're going to spend some time going</p> <p>8 through your opinions as -- as stated in your report. So</p> <p>9 I'm going to have you turn to Page 2, and specifically the</p> <p>10 fourth section of your report in Paragraph 12, you don't</p> <p>11 have any opinions that are stated in the earlier parts of</p> <p>12 your report prior to this paragraph; is that correct?</p> <p>13 A. Correct.</p> <p>14 Q. In Paragraph 12 you state that in July 2018 the</p> <p>15 FDA announced a voluntary recall of Valsartan, including</p> <p>16 Valsartan-containing drugs, due to contaminants NDEA and</p> <p>17 NDMA. What is your basis for that statement?</p> <p>18 A. That information is found on the FDA website.</p> <p>19 Q. What do you understand the term contaminants to</p> <p>20 mean?</p> <p>21 A. These contaminants were found in unacceptable</p> <p>22 levels and probable human carcinogens and do not belong in</p> <p>23 the medication.</p> <p>24 Q. I want to make sure I understood your answer.</p> <p>25 MS. ISIDRO: Can you read back the question and</p>

<p style="text-align: right;">Page 94</p> <p>1 the answer for me, please?</p> <p>2 (The requested portion was read back.)</p> <p>3 BY MS. ISIDRO:</p> <p>4 Q. Am I understanding you correctly that you</p> <p>5 understand the term contaminants to mean any substance that</p> <p>6 does not belong in the medication?</p> <p>7 MR. HANSEL: Object to the form.</p> <p>8 A. In the scope of this case, a -- the contaminant</p> <p>9 is a substance that was -- should not have been in the</p> <p>10 medication and not consistent with the referenced labeled</p> <p>11 product.</p> <p>12 BY MS. ISIDRO:</p> <p>13 Q. So that is how you are using the word</p> <p>14 contaminants in this report?</p> <p>15 MR. HANSEL: Object to the form. Asked and</p> <p>16 answered.</p> <p>17 A. I've answered the question.</p> <p>18 BY MS. ISIDRO:</p> <p>19 Q. I just want to make sure I'm understanding your</p> <p>20 answer.</p> <p>21 MR. HANSEL: Object to form.</p> <p>22 BY MS. ISIDRO:</p> <p>23 Q. Have I stated that correctly?</p> <p>24 MR. HANSEL: Object to form.</p> <p>25 A. Please restate so I can be sure I -- I understand</p>	<p style="text-align: right;">Page 96</p> <p>1 definition of the term contaminants?</p> <p>2 A. Specifically, no.</p> <p>3 Q. In the next sentence you say these contaminants</p> <p>4 are probable human carcinogens according to the</p> <p>5 International Agency for Research on Cancer classification.</p> <p>6 Are -- so are you relying on IARC's classification in that</p> <p>7 statement?</p> <p>8 A. Yes.</p> <p>9 Q. Have you independently assessed the</p> <p>10 carcinogenicity of NDEA or NDMA?</p> <p>11 A. Not independently.</p> <p>12 Q. Are you relying on anything other than the IARC</p> <p>13 classification in making that statement in your report?</p> <p>14 MR. HANSEL: Object to the form.</p> <p>15 A. The IARC classification is public information</p> <p>16 which is what I relied on to make that statement.</p> <p>17 BY MS. ISIDRO:</p> <p>18 Q. Okay. And you didn't rely on anything else for</p> <p>19 purposes of that statement?</p> <p>20 MR. HANSEL: Object to the form.</p> <p>21 A. Yes.</p> <p>22 BY MS. ISIDRO:</p> <p>23 Q. Yes. I'm sorry, yes, that's correct?</p> <p>24 A. Yes.</p> <p>25 MR. HANSEL: Object to the form.</p>
<p style="text-align: right;">Page 95</p> <p>1 the way you restated it.</p> <p>2 MS. ISIDRO: Can you read it back, please?</p> <p>3 (The requested portion was read back.)</p> <p>4 BY MS. ISIDRO:</p> <p>5 Q. I just want to understand, Doctor, whether --</p> <p>6 what you've discussed in that prior response is a</p> <p>7 description of how you personally are using the term</p> <p>8 contaminants in your report.</p> <p>9 A. Uh-huh. So a contaminant is any substance that</p> <p>10 is in the medication that should not have been there, not</p> <p>11 consistent with the referenced label product, and</p> <p>12 inconsistent with the safety and efficacy of the referenced</p> <p>13 labeled product.</p> <p>14 Q. Thank you. What are you relying on for purposes</p> <p>15 of your definition of contaminants?</p> <p>16 A. My industry knowledge, my pharmacy background, my</p> <p>17 education, studies, and professional scope in my career.</p> <p>18 Q. Anything else?</p> <p>19 A. No.</p> <p>20 Q. You're not relying on any specific FDA</p> <p>21 regulations for the purpose of that definition?</p> <p>22 A. The scope of my career relies -- you know,</p> <p>23 involves referring to FDA information so.</p> <p>24 Q. Are there specific FDA regulations that you are</p> <p>25 referring to in terms of your understanding of the</p>	<p style="text-align: right;">Page 97</p> <p>1 BY MS. ISIDRO:</p> <p>2 Q. Okay. Apart from any alleged presence of NDEA or</p> <p>3 NDMA in Valsartan-containing drugs, are you offering any</p> <p>4 criticism of Valsartan-containing drugs?</p> <p>5 A. Valsartan -- as long as they're being used for</p> <p>6 their intended FDA labeled use, no.</p> <p>7 Q. The next section, Section 5, talks about</p> <p>8 background on TPP pharmacy benefits and Paragraphs 14</p> <p>9 through 18 specifically talk about TPPs; is that correct?</p> <p>10 A. Yes.</p> <p>11 Q. What are you relying on in making the statements</p> <p>12 that you make in Paragraphs 14 through 18 with respect to</p> <p>13 TPPs?</p> <p>14 A. I'm relying on the information I've listed in</p> <p>15 Appendix A.</p> <p>16 Q. Can we -- can you please look at that appendix</p> <p>17 and identify for me which of the items listed on Appendix A</p> <p>18 you're relying on for purposes of paragraphs 14 through 18</p> <p>19 of your report?</p> <p>20 A. Yeah. So I have listed in the appendix</p> <p>21 experts -- excerpts, excuse me, of data, MSP data --</p> <p>22 Q. That's the one that says Detail Claim Report, HMO</p> <p>23 fields added, July 6, 2021?</p> <p>24 A. Yes. And the other items would be the</p> <p>25 coordination of benefits, third-party liability.</p>

Page 98	Page 100
<p>1 Q. Okay. That's further up on the list on Page 1 of</p> <p>2 Appendix A?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. Anything else?</p> <p>5 A. And then further down where it says MADA claims</p> <p>6 for the recalled Valsartan.</p> <p>7 Q. Okay. That's the last item on -- on that page,</p> <p>8 MADA claims data for recalled Valsartan --</p> <p>9 A. Yes.</p> <p>10 Q. -- four spreadsheets?</p> <p>11 A. Yes. And then on the next page there are</p> <p>12 additional items referenced, fourth and fifth down. The</p> <p>13 recall status of NDCs.</p> <p>14 Q. So you mentioned fourth and fifth down. Is that</p> <p>15 MADA Third Party Payor Plaintiff's Fact Sheet, and MSP</p> <p>16 Third Party Payor Plaintiff's Fact Sheet?</p> <p>17 A. Yeah.</p> <p>18 Q. And then two down from that, was it the recall</p> <p>19 status of NDCs listed? Is that the one you referred to?</p> <p>20 A. Uh-huh.</p> <p>21 Q. Okay.</p> <p>22 A. Yes.</p> <p>23 Q. Anything else?</p> <p>24 A. My own experience from being an expert in this</p> <p>25 field and consulting and knowing how these entities work.</p>	<p>1 A. The American Journal of Managed Care, ASHP,</p> <p>2 Coordination of Benefits, Formulary Development, The</p> <p>3 Journal of Managed Care, Drug -- Navigating Drug</p> <p>4 Formularies and Pharmacy Benefit Management, the Orange</p> <p>5 Book, Principles of a Sound Drug Formulary, and the U.S.</p> <p>6 Food and Drug Administration Development Approval Process.</p> <p>7 Q. The next section of your report, Paragraphs 21</p> <p>8 through 28, discusses prescription drug formularies; is</p> <p>9 that right?</p> <p>10 A. Yes.</p> <p>11 Q. What did you rely on in formulating the</p> <p>12 statements in paragraphs 21 through 28 of your report?</p> <p>13 A. The same ones I gave you for PBM.</p> <p>14 Q. Okay.</p> <p>15 A. Including my knowledge, experience, and education</p> <p>16 in my professional capacity.</p> <p>17 Q. Okay. And nothing additional with respect to</p> <p>18 Paragraphs 21 and 28, is that correct, as compared with</p> <p>19 Paragraphs 19 and 20?</p> <p>20 A. Just whatever falls under the scope of my</p> <p>21 professional capacity and my day-to-day functions.</p> <p>22 Q. And would you consider Paragraphs 14 through 28</p> <p>23 to be background for your opinions in this litigation?</p> <p>24 MR. HANSEL: Object to the form. Calls for a</p> <p>25 legal conclusion.</p>
Page 99	Page 101
<p>1 Q. Have we now discussed all of the bases for your</p> <p>2 statements in Paragraphs 14 through 18 --</p> <p>3 MR. HANSEL: Object to the form.</p> <p>4 BY MS. ISIDRO:</p> <p>5 Q. -- of your report?</p> <p>6 A. All of my materials reviewed are in the appendix,</p> <p>7 so for my -- for the entirety of my expert report. So I've</p> <p>8 answered your question, you know, to the best of my</p> <p>9 knowledge at this point, but I have -- I'd have to go back</p> <p>10 and study each of the items in the appendix very closely to</p> <p>11 ensure that I haven't missed a point in those sections, but</p> <p>12 for purposes of our discussion, I have pointed out those</p> <p>13 that I believe are relevant.</p> <p>14 Q. All right. The next section of your report,</p> <p>15 Paragraphs 19 and 20, deals with PBMs; is that correct?</p> <p>16 A. Right.</p> <p>17 Q. And what did you rely on in formulating the</p> <p>18 statements that you've included on Paragraphs 19 and 20 of</p> <p>19 your report?</p> <p>20 A. My professional experience, my pharmacy knowledge</p> <p>21 and education, and the materials in Appendix A.</p> <p>22 Q. And with respect to the materials in Appendix A,</p> <p>23 which of the materials listed in Appendix A formed the</p> <p>24 basis for your statements in Paragraphs 19 and 20 of your</p> <p>25 report?</p>	<p>1 A. Please repeat the question?</p> <p>2 MS. ISIDRO: Could you read it back, please?</p> <p>3 (The requested portion was read back.)</p> <p>4 MR. HANSEL: Same objection.</p> <p>5 A. They can serve as a background or they're</p> <p>6 information pertinent to the -- the opinion, relevant and</p> <p>7 pertinent.</p> <p>8 BY MS. ISIDRO:</p> <p>9 Q. In Paragraphs 29 to 32 you make various</p> <p>10 statements concerning the Orange Book, correct?</p> <p>11 A. 29 through -- well, it goes beyond 32.</p> <p>12 BY MS. ISIDRO:</p> <p>13 Q. Okay.</p> <p>14 A. But yes.</p> <p>15 Q. Okay. You have a Section D in your report titled</p> <p>16 Orange Book and that goes 29 through 32; is that correct?</p> <p>17 A. In Section D, yes.</p> <p>18 Q. Okay. What is the Orange Book?</p> <p>19 A. The Orange Book, also known as the Approved Drug</p> <p>20 Products with Therapeutic Equivalence Evaluation, is a list</p> <p>21 of FDA approved drug products and they're -- approved for</p> <p>22 marketing as -- in the United States as they're labeled --</p> <p>23 as their label indication.</p> <p>24 Q. Doctor, as part of what PBMs do, do PBMs develop</p> <p>25 formularies?</p>

<p style="text-align: right;">Page 102</p> <p>1 A. Yes.</p> <p>2 Q. In doing so, do TP -- excuse me. Withdrawn.</p> <p>3 Do TPPs review and either adopt a formulary as is</p> <p>4 or do they customize the PBM formulary?</p> <p>5 MR. HANSEL: Object to the form.</p> <p>6 A. Could you be more specific?</p> <p>7 BY MS. ISIDRO:</p> <p>8 Q. What specificity are you looking for?</p> <p>9 A. When you say customize.</p> <p>10 Q. Do TPPs make any changes to the formularies that</p> <p>11 PBMs develop?</p> <p>12 A. TPPs, they're prescription -- the prescription</p> <p>13 benefit design is up to the client and they're -- what's</p> <p>14 included or excluded in that benefit design can be tied</p> <p>15 into the formulary.</p> <p>16 Q. Is it possible for a TPP to use its own P&T</p> <p>17 committee?</p> <p>18 A. If they have a P&T committee.</p> <p>19 Q. In fact, you note in your Footnote 2 of your</p> <p>20 report that in some cases the development and management of</p> <p>21 a drug formulary is done in-house where the TPP will use</p> <p>22 its own P&T committee and might consult with the PPM,</p> <p>23 correct?</p> <p>24 A. If they have their own P&T committee.</p> <p>25 Q. And you do state that in Footnote 2 of your</p>	<p style="text-align: right;">Page 104</p> <p>1 A. Drug monographs, product labels, submitted</p> <p>2 applications for approval, status within the Orange</p> <p>3 Book -- Book.</p> <p>4 Q. Is cost a factor?</p> <p>5 A. P&T committees make their decisions based on</p> <p>6 clinical merit.</p> <p>7 Q. So in your -- the diagram that you include in</p> <p>8 Paragraph 28 in the fourth tier down --</p> <p>9 A. Uh-huh.</p> <p>10 Q. -- it's titled P&2 -- P&T review meetings. Do</p> <p>11 you see that?</p> <p>12 A. Yes.</p> <p>13 Q. It lists safety, efficacy, and cost. What does</p> <p>14 that refer to, that reference to cost there?</p> <p>15 A. P&T committees make their decisions primarily</p> <p>16 based on clinical efficacy, ensuring that the drug that is</p> <p>17 going to be considered for placement on the formulary is</p> <p>18 safe and effective. Additional functions may include cost</p> <p>19 as it pertains to reimbursement of the claim.</p> <p>20 Q. So that is one of the factors that can be</p> <p>21 considered via a P&T committee, correct?</p> <p>22 A. The primary factors are based on clinical merit</p> <p>23 and not cost.</p> <p>24 Q. So you would not consider cost a primary factor,</p> <p>25 correct?</p>
<p style="text-align: right;">Page 103</p> <p>1 report, correct?</p> <p>2 A. I have agreed.</p> <p>3 Q. Do you have any knowledge as to what share of the</p> <p>4 proposed TPP class members developed their own formularies</p> <p>5 versus using a formulary developed by a PBM?</p> <p>6 A. No, I do not.</p> <p>7 Q. Short of making an inquiry into each -- each TPP</p> <p>8 class members whose formulary included the at issue</p> <p>9 Valsartan, is there any way to tell whether it was the PBM</p> <p>10 or the TPP to decided whether Valsartan should be included?</p> <p>11 A. No, I will not speculate.</p> <p>12 Q. In Paragraph 25 of your report -- it's the bottom</p> <p>13 of Page 4 and top of Page 5.</p> <p>14 A. Uh-huh.</p> <p>15 Q. You mention that the P&T committee is required to</p> <p>16 base formulary decisions on scientific evidence, standards</p> <p>17 of practice, peer reviewed medical literature, accepted</p> <p>18 clinical practice guidelines, and other appropriate</p> <p>19 information.</p> <p>20 What is other appropriate information?</p> <p>21 A. Data specific to the drug they are reviewing. It</p> <p>22 could include clinical studies.</p> <p>23 Q. Anything else?</p> <p>24 A. Yes. It could include other items.</p> <p>25 Q. Such as?</p>	<p style="text-align: right;">Page 105</p> <p>1 A. P&T committees are unbiased advisory boards</p> <p>2 reviewing drug information based on the clinical merit of</p> <p>3 the -- that's their primary function. Once that is</p> <p>4 completed, they can include costs or may -- may or may not</p> <p>5 include that as part of their discussion.</p> <p>6 Q. Okay. And you did include it as part of the</p> <p>7 diagram in Paragraph 28?</p> <p>8 A. Uh-huh.</p> <p>9 Q. Correct?</p> <p>10 A. Yes.</p> <p>11 Q. At the bottom of that diagram, the very last tier</p> <p>12 of that diagram, you refer to relevant stakeholders. Who</p> <p>13 are those relevant stakeholders?</p> <p>14 A. Whoever the entity is deciding on the formulary,</p> <p>15 whether to adopt that formulary as part of their</p> <p>16 prescription benefit.</p> <p>17 Q. The Orange Book is published by the FDA, correct?</p> <p>18 A. Correct.</p> <p>19 Q. And the Orange Book lists drug products that are</p> <p>20 approved by FDA on the basis of safety and effectiveness;</p> <p>21 is that correct?</p> <p>22 A. Correct.</p> <p>23 Q. The Orange Book also contains therapeutic</p> <p>24 equivalence evaluations for approved generic prescription</p> <p>25 drug products; is that correct?</p>

<p style="text-align: right;">Page 106</p> <p>1 A. Yes.</p> <p>2 Q. Who makes those therapeutic equivalence</p> <p>3 evaluations?</p> <p>4 A. The FDA.</p> <p>5 Q. When a generic drug manufacturer files an ANDA,</p> <p>6 one of the things that they must demonstrate to FDA in that</p> <p>7 ANDA is bioequivalence, correct?</p> <p>8 A. That was not within the scope of my report, but I</p> <p>9 understand that to be part of the requirement.</p> <p>10 Q. Okay. So that consideration is -- is outside the</p> <p>11 scope of your report and your opinions in this litigation,</p> <p>12 correct?</p> <p>13 MR. HANSEL: Object to the form.</p> <p>14 A. As I said, it is part of the process for filing</p> <p>15 an ANDA or applying for ANDA.</p> <p>16 MS. ISIDRO: Can you please read back the answer</p> <p>17 that mentioned outside of the scope of the report?</p> <p>18 MR. HANSEL: And the question also.</p> <p>19 MS. ISIDRO: Sure. Please.</p> <p>20 (The requested portion was read back.)</p> <p>21 BY MS. ISIDRO:</p> <p>22 Q. For Section D of your report, Paragraphs 29</p> <p>23 through 32, what did you rely on in formulating those</p> <p>24 paragraphs of your report?</p> <p>25 A. FDA information.</p>	<p style="text-align: right;">Page 108</p> <p>1 Q. Okay. But not any of the other items listed on</p> <p>2 Appendix A, other --</p> <p>3 A. It could have been --</p> <p>4 Q. -- than the two that we've discussed?</p> <p>5 A. It could have been -- all of the items in the</p> <p>6 appendix can have played a role in forming the entirety of</p> <p>7 my discussion and expert opinion. That's why they're</p> <p>8 listed there.</p> <p>9 Q. Okay. Did the MADA Third Party Payor Plaintiff's</p> <p>10 Fact Sheet form the basis for any of your -- any of the</p> <p>11 information stated in Paragraphs 29 through 32 of your</p> <p>12 report?</p> <p>13 A. Not as it pertains to the explanation of the</p> <p>14 Orange Book, the description of the Orange Book.</p> <p>15 Q. Is there another aspect to Paragraphs 29 through</p> <p>16 32 that it does touch upon?</p> <p>17 A. By it, you mean -- can you be more clear?</p> <p>18 Q. The MADA Third Party Payor Plaintiff's Fact</p> <p>19 Sheet.</p> <p>20 MR. HANSEL: Object to the form.</p> <p>21 A. Could you please repeat the question?</p> <p>22 MS. ISIDRO: Sorry, could you read the question?</p> <p>23 I think you were asking for the court reporter to read</p> <p>24 the question back.</p> <p>25 (The requested portion was read back.)</p>
<p style="text-align: right;">Page 107</p> <p>1 Q. Which specific FDA information?</p> <p>2 A. On ANDA process, on NDA generic drugs.</p> <p>3 Q. Would the FDA information that you relied on be</p> <p>4 listed in Appendix A of your report?</p> <p>5 A. I believe it is listed at -- that's Page 2, U.S.</p> <p>6 Food and Drug Administration Development Approval Process.</p> <p>7 Q. Okay. Anything else?</p> <p>8 A. I relied on my knowledge and experience in the</p> <p>9 industry, knowing how the process works.</p> <p>10 Q. Okay. Did you also rely on the Orange Book</p> <p>11 preface that's listed in your Appendix A?</p> <p>12 A. Yes, I referenced the Orange Book.</p> <p>13 Q. I'm sorry, I miss -- I think I misheard you. I</p> <p>14 thought the only item that you had mentioned from</p> <p>15 Appendix A was the U.S. Food and Drug Administration</p> <p>16 Development Approval process?</p> <p>17 A. Clearly the Orange Book is listed in the</p> <p>18 Appendix A as well, so let me clarify and say that I</p> <p>19 referenced that in addition. I think that's --</p> <p>20 Q. Okay.</p> <p>21 A. -- quite obvious.</p> <p>22 Q. So it would be those two items from Appendix A,</p> <p>23 correct?</p> <p>24 A. In addition to my knowledge and experience,</p> <p>25 understanding how the process works.</p>	<p style="text-align: right;">Page 109</p> <p>1 MS. ISIDRO: I'll restate the question.</p> <p>2 BY MS. ISIDRO:</p> <p>3 Q. Does the MADA Third Party Payor Plaintiff's Fact</p> <p>4 Sheet form the basis of any aspect of your statements in</p> <p>5 Paragraphs 29 through 32 of your report?</p> <p>6 A. No. Not the basis.</p> <p>7 Q. In Paragraphs 33 through 41 of your report, you</p> <p>8 discuss definitions and significance of therapeutic</p> <p>9 equivalence code; is that correct?</p> <p>10 A. That is correct.</p> <p>11 Q. What did you rely on in formulating your</p> <p>12 Paragraphs 33 through 41 of your report?</p> <p>13 MR. HANSEL: Object to the form.</p> <p>14 A. The FDA information on the Orange Book.</p> <p>15 BY MS. ISIDRO:</p> <p>16 Q. Uh-huh.</p> <p>17 A. And the explanation of therapeutic equivalence</p> <p>18 codes, public information.</p> <p>19 Q. And just to make sure I understand the</p> <p>20 explanation of therapeutic equivalence codes, do you mean</p> <p>21 within the Orange Book itself or are you referring to</p> <p>22 something different?</p> <p>23 A. The TE codes or therapeutic equivalence codes are</p> <p>24 present in the Orange Book.</p> <p>25 Q. Okay. So the -- so those are the -- that's what</p>

<p style="text-align: right;">Page 110</p> <p>1 you're referring to?</p> <p>2 A. As I understand your question, yes.</p> <p>3 Q. Okay. In Paragraphs 42 and 43 you discuss</p> <p>4 criteria for entry into the Orange Book; is that correct?</p> <p>5 A. Yes.</p> <p>6 Q. What is the basis for your statements in</p> <p>7 Paragraphs 42 and 43?</p> <p>8 A. The FDA process established for drugs seeking</p> <p>9 approval.</p> <p>10 Q. Is that the last item listed on Appendix A of</p> <p>11 your report?</p> <p>12 MR. HANSEL: Object to the form.</p> <p>13 A. That has the FDA item on the -- on the appendix,</p> <p>14 yes, but as I said, all of the items in my appendix</p> <p>15 could've played a role in my -- all of my -- entirety of my</p> <p>16 expert opinion.</p> <p>17 BY MS. ISIDRO:</p> <p>18 Q. I was asking specifically the response you gave</p> <p>19 to the prior question.</p> <p>20 MS. ISIDRO: So could you read it back, that</p> <p>21 prior question and answer?</p> <p>22 (The requested portion was read back.)</p> <p>23 MR. HANSEL: Object to the form.</p> <p>24 BY MS. ISIDRO:</p> <p>25 Q. So, Dr. Panagos, in that response when you said</p>	<p style="text-align: right;">Page 112</p> <p>1 MS. ISIDRO: Could you please read back the last</p> <p>2 question before the speaking objection, and I don't</p> <p>3 believe there was an answer, but if there was please</p> <p>4 read that too.</p> <p>5 (The requested portion was read back.)</p> <p>6 MR. HANSEL: Object to the form.</p> <p>7 A. You're referring to the Orange Book, the process</p> <p>8 by which a drug can gain approval and list -- to be listed</p> <p>9 in the Orange Book is public information on brand and</p> <p>10 generic drugs and the processing must follow as established</p> <p>11 by the FDA. It's an authoritative source.</p> <p>12 BY MS. ISIDRO:</p> <p>13 Q. So, Doctor, in making your statements in</p> <p>14 Paragraph 42 of your report, I understand your response to</p> <p>15 be that you have relied on the U.S. Food and Drug</p> <p>16 Administration Development Approval Process. Am I</p> <p>17 understanding that to be -- am I correctly understanding</p> <p>18 that to be one of the bases for your statement in Paragraph</p> <p>19 42 of your report?</p> <p>20 A. One of the bases.</p> <p>21 Q. Okay. What are the other bases for your</p> <p>22 statement in Paragraph 42 of your report?</p> <p>23 A. The Orange Book itself, my experience, education,</p> <p>24 and professional capacity and -- and -- and my day-to-day</p> <p>25 experience in this field.</p>
<p style="text-align: right;">Page 111</p> <p>1 the FDA process established for drugs seeking approval,</p> <p>2 were you referring to the last item that's listed in the</p> <p>3 Appendix A of your report or were you referring to</p> <p>4 something else?</p> <p>5 MR. HANSEL: Object to the form. Asked and</p> <p>6 answered repeatedly.</p> <p>7 The -- the witness has testified numerous times</p> <p>8 about things she relied on for the entirety of her</p> <p>9 report, and this repeated attempt to pigeonhole her is</p> <p>10 just unfair and it -- could we stipulate that her</p> <p>11 previous testimony about what she's relied on for her</p> <p>12 entire report will apply to each question about what</p> <p>13 she relied on for a particular paragraph?</p> <p>14 MS. ISIDRO: Let the record reflect that counsel</p> <p>15 is making an inappropriate speaking objection.</p> <p>16 Defendants are entitled to explore the basis for the</p> <p>17 statements and conclusions in Dr. Panagos's report as</p> <p>18 a proffered expert in this litigation.</p> <p>19 MR. HANSEL: Will you stipulate?</p> <p>20 MS. ISIDRO: So -- we will not stipulate to waive</p> <p>21 our rights to explore the basis for her statements and</p> <p>22 conclusions in her report.</p> <p>23 MR. DORNER: Hello. This is Drew Dorner. ZHP</p> <p>24 will not stipulate either to your proposed</p> <p>25 stipulation.</p>	<p style="text-align: right;">Page 113</p> <p>1 Q. Any other bases that you're relying on for your</p> <p>2 statements in Paragraph 42 of your report?</p> <p>3 A. No.</p> <p>4 Q. And what are you relying on for your statements</p> <p>5 in Paragraph 43 of your report?</p> <p>6 A. The same.</p> <p>7 Q. Okay. You state in Paragraph 44 that a generic</p> <p>8 drug is a copy of a branded drug in terms of dosage,</p> <p>9 administration, and performance. What is your basis for</p> <p>10 that statement?</p> <p>11 A. My understanding of a generic drug from my</p> <p>12 education, my experience, and the information on -- in --</p> <p>13 I've listed in Appendix A.</p> <p>14 Q. And which of the items listed in Appendix A are</p> <p>15 you relying on for the statement that a generic drug is a</p> <p>16 copy of a branded drug in terms of dosage, administration,</p> <p>17 and performance?</p> <p>18 A. All of the information except for the claims</p> <p>19 data.</p> <p>20 Q. So that includes -- so you are relying for</p> <p>21 purposes of that statement on the MADA Third Party</p> <p>22 Player -- Third Party Payor Plaintiff's Fact Sheet?</p> <p>23 A. No. I include that as part of the claim, so let</p> <p>24 me clarify.</p> <p>25 Q. Okay.</p>

<p style="text-align: right;">Page 114</p> <p>1 A. Not the Plaintiff Fact Sheet.</p> <p>2 Q. Okay. Because you also have an item called MADA</p> <p>3 Claims Data for Recalled Valsartan.</p> <p>4 A. Those go together.</p> <p>5 Q. Okay. So you did not rely on that? You did</p> <p>6 not -- did you rely on the MSP Third Party Payor</p> <p>7 Plaintiff's Fact Sheet?</p> <p>8 A. No.</p> <p>9 Q. Okay. Other than those three items in Appendix A</p> <p>10 to your report, you relied on all of the other items for</p> <p>11 purposes of the statement that a generic drug is a copy of</p> <p>12 a branded drug in terms of dosage, administration, and</p> <p>13 performance?</p> <p>14 A. Including my knowledge, education, all --</p> <p>15 Q. Did --</p> <p>16 A. -- and -- yeah.</p> <p>17 Q. Did you rely on the FIN Declaration for purposes</p> <p>18 of that statement?</p> <p>19 A. No.</p> <p>20 Q. Okay. In Paragraph 44 you go on to say that</p> <p>21 generic drugs must be bioequivalent to the branded drug,</p> <p>22 meaning the generic drug will work the same way in the body</p> <p>23 and be as safe and effective as the brand name drug.</p> <p>24 A. That is correct.</p> <p>25 Q. What are you relying on in making that statement</p>	<p style="text-align: right;">Page 116</p> <p>1 because they are deemed to be safe and effective. It is</p> <p>2 really -- the -- the foundation or the basis that</p> <p>3 determined whether a generic drug meets the criteria for</p> <p>4 inclusion on a -- for consideration on a formulary, they</p> <p>5 are listed in the Orange Book or not.</p> <p>6 BY MS. ISIDRO:</p> <p>7 Q. Is it specifically the FDA's therapeutic</p> <p>8 equivalence evaluation that -- that determines whether a</p> <p>9 generic equivalent can be substituted?</p> <p>10 MR. HANSEL: Object to the form.</p> <p>11 A. They must have an approved ANDA and have a</p> <p>12 therapeutic equivalence code assigned to the medication</p> <p>13 that allows them to be considered substitutable.</p> <p>14 BY MS. ISIDRO:</p> <p>15 Q. And which are the codes that allow them to be</p> <p>16 considered substitutable?</p> <p>17 A. AB.</p> <p>18 Q. You state in Paragraph 46 that TPPs and P&T</p> <p>19 committees expressly rely upon the manufacturer's</p> <p>20 compliance with all applicable standards, obligations, and</p> <p>21 regulations.</p> <p>22 What is your basis for that statement in</p> <p>23 Paragraph 46?</p> <p>24 MR. HANSEL: Object to the form.</p> <p>25 A. The information presented to the FDA for approval</p>
<p style="text-align: right;">Page 115</p> <p>1 in Paragraph 44?</p> <p>2 MR. HANSEL: Object to the form.</p> <p>3 A. Relying on my education, my degrees, my licensure</p> <p>4 as a pharmacist. It's a critical component to performing</p> <p>5 my day-to-day functions and understanding that foundational</p> <p>6 component, what a generic drug is. So I -- I rely on my</p> <p>7 education and my experience and the items I've listed in</p> <p>8 the appendix.</p> <p>9 BY MS. ISIDRO:</p> <p>10 Q. What FDA regulation or regulations define the</p> <p>11 term bioequivalent?</p> <p>12 A. I was not asked to study that, so -- so I'm not</p> <p>13 going to answer that at this time. I'd have to study the</p> <p>14 FDA regulations very closely to be able to give a</p> <p>15 thoughtful and complete answer to -- to that question.</p> <p>16 Q. Paragraph 45 you state that the substitution of</p> <p>17 generic equivalents, drugs considered bioequivalent by FDA,</p> <p>18 are encouraged by PBMs to provide the best care at an</p> <p>19 affordable cost.</p> <p>20 What is your basis for that statement?</p> <p>21 MR. HANSEL: Object to the form.</p> <p>22 A. The Orange Book lists drugs that are approved to</p> <p>23 their referenced listed drug product to be the same and</p> <p>24 effective and to be considered -- a consideration for the</p> <p>25 formulary. Those drugs are considered substitutable</p>	<p style="text-align: right;">Page 117</p> <p>1 by an ANDA application is presented by the manufacturer who</p> <p>2 is responsible for the information they provide.</p> <p>3 BY MS. ISIDRO:</p> <p>4 Q. And what is your answer based on?</p> <p>5 MR. HANSEL: Object to the form.</p> <p>6 A. The application is submitted by the manufacturer</p> <p>7 who is responsible for the information they provide the FDA</p> <p>8 to be considered for approval. That includes all aspects</p> <p>9 related to that application.</p> <p>10 BY MS. ISIDRO:</p> <p>11 Q. What is your support for that response?</p> <p>12 MR. HANSEL: Object to the form.</p> <p>13 A. Manufacturers are responsible for their</p> <p>14 medication. They're responsible for the quality control,</p> <p>15 ensuring that that medication is safe and effective to --</p> <p>16 when they're applying for that approval -- seeking approval</p> <p>17 by the FDA. It's their responsibility to ensure that it's</p> <p>18 safe and effective.</p> <p>19 BY MS. ISIDRO:</p> <p>20 Q. Is that your own opinion?</p> <p>21 MR. HANSEL: Object to the form.</p> <p>22 A. In my professional capacity, that is what I</p> <p>23 believe to be correct.</p> <p>24 BY MS. ISIDRO:</p> <p>25 Q. Within Paragraph 46 of your report, what are you</p>

<p style="text-align: right;">Page 118</p> <p>1 relying on in making a representation as to what TPPs</p> <p>2 expressly rely upon?</p> <p>3 MR. HANSEL: Object to the form.</p> <p>4 A. So 46 refers to the P&T committee, which the P&T</p> <p>5 committee will make the decision whether the drug will be</p> <p>6 considered for the formulary or not.</p> <p>7 I don't understand your question if you're asking</p> <p>8 something else.</p> <p>9 BY MS. ISIDRO:</p> <p>10 Q. Sure. There's -- there's a statement in</p> <p>11 Paragraph 46 of your report that TPPs and P&T committees</p> <p>12 expressly rely upon the manufacturer's compliance with all</p> <p>13 applicable standards, obligations, and regulations.</p> <p>14 A. Correct. Via the NDA. The manufacturer has to</p> <p>15 provide that information to the FDA via their ANDA</p> <p>16 application to be considered for approval and that's the</p> <p>17 information that's relied upon for the approval.</p> <p>18 Q. Okay. And you say that that information is -- is</p> <p>19 expressly relied upon by the TPPs and the P&T committees,</p> <p>20 correct?</p> <p>21 A. That information is relied upon as it's provided</p> <p>22 in their application submitted to the FDA for approval.</p> <p>23 Q. But am I correct in saying that Paragraph 46 of</p> <p>24 your report states that that information is expressly</p> <p>25 relied upon by TPPs and P&T committees?</p>	<p style="text-align: right;">Page 120</p> <p>1 the formulary.</p> <p>2 Q. Can you point to any document in which a TPP</p> <p>3 expressly relies upon the manufacturer's compliance with</p> <p>4 all applicable standards, obligations and regulations?</p> <p>5 A. That is done via -- referencing the Orange Book</p> <p>6 and the approval status of the drugs.</p> <p>7 Q. So when you say that they expressly rely upon</p> <p>8 that information, am I understanding correctly that what</p> <p>9 you mean by that statement is that they --</p> <p>10 A. It is the responsibility of the manufacturer to</p> <p>11 provide that information on their drug application, follow</p> <p>12 the process established by the FDA for their drugs to be</p> <p>13 considered for approval in the United States and considered</p> <p>14 for coverage on the drug formulary.</p> <p>15 MS. ISIDRO: Can you please read back the prior</p> <p>16 question and answer, not this one.</p> <p>17 (The requested portion was read back.)</p> <p>18 BY MS. ISIDRO:</p> <p>19 Q. Can you point to any document in which a P&T</p> <p>20 committee expressly relies upon the manufacturer's</p> <p>21 compliance with all applicable standards, obligations, and</p> <p>22 regulations?</p> <p>23 MR. HANSEL: Object to the form.</p> <p>24 A. The Orange Book is a representation of a list of</p> <p>25 drugs approved safe and effective for use in the United</p>
<p style="text-align: right;">Page 119</p> <p>1 A. It's relied upon in that it -- it's provided to</p> <p>2 the applic- -- in the application for approval.</p> <p>3 Q. Okay. Do you see the word expressly in Paragraph</p> <p>4 46 of your report?</p> <p>5 A. Yes.</p> <p>6 Q. What did you mean by the word expressly in</p> <p>7 Paragraph 46 of your report?</p> <p>8 A. That it is -- that it is the responsibility of</p> <p>9 the manufacturer to provide all the information, in</p> <p>10 conjunction with their medication, seeking approval by the</p> <p>11 FDA. It is their responsibility to do that.</p> <p>12 Q. And Paragraph 46 says that TPPs and P&T</p> <p>13 committees expressly rely, correct?</p> <p>14 A. Right. Because the manufacturers are providing</p> <p>15 that information on their ANDA application seeking approval</p> <p>16 by the FDA.</p> <p>17 Q. So am I not understanding your sentence in</p> <p>18 Paragraph 46 correctly, that the TPPs and the P&Ts are the</p> <p>19 ones who expressly rely upon the information you're</p> <p>20 referencing?</p> <p>21 A. Once that medication is approved, because they</p> <p>22 have provided that -- the manufacturer has complied with</p> <p>23 all the requirements needed for approval, that medication</p> <p>24 is listed in the Orange Book as having complied and so they</p> <p>25 will -- that suffices the requirement for consideration to</p>	<p style="text-align: right;">Page 121</p> <p>1 States.</p> <p>2 BY MS. ISIDRO:</p> <p>3 Q. Is the Orange Book issued by P&T committees?</p> <p>4 A. No. It's issued by the FDA.</p> <p>5 Q. Right. So the P&T committee is not making any</p> <p>6 express statements in the Orange Book, correct?</p> <p>7 A. No, they're not.</p> <p>8 Q. Have you read the ANDA for any</p> <p>9 Valsartan-containing drug?</p> <p>10 A. No.</p> <p>11 Q. You state in Paragraph 47 that the AB rating in</p> <p>12 the FDA Orange Book based as it is on the generic drug</p> <p>13 manufacturer's ANDA represents a manufacturer's warranty to</p> <p>14 TPPs and P&T committees for placement on a prescription</p> <p>15 drug formulary.</p> <p>16 What do you mean by the term warranty in</p> <p>17 Paragraph 47?</p> <p>18 MR. HANSEL: Objection. Calls for a legal</p> <p>19 conclusion.</p> <p>20 MS. ISIDRO: It's a term she's used in her</p> <p>21 report. I'm entitled to ask her what she means by it</p> <p>22 when she uses it in her report.</p> <p>23 Can you please read back the question?</p> <p>24 MR. HANSEL: Can we stipulate that every time you</p> <p>25 ask a question about warranty I'm making a continuing</p>

<p style="text-align: right;">Page 122</p> <p>1 objection that it's -- I object to the form because it</p> <p>2 is calling for a legal conclusion? Will you stipulate</p> <p>3 to that continuing objection so I don't have to repeat</p> <p>4 myself every time you ask a question about warranty.</p> <p>5 MS. ISIDRO: No. I will not stipulate to that</p> <p>6 unless she will withdraw the use of the term warranty</p> <p>7 from her report in which case I don't have to ask</p> <p>8 about it anymore.</p> <p>9 ZOOM PARTICIPANT: There's a pending question.</p> <p>10 Does the witness remember the question?</p> <p>11 MS. ISIDRO: I was just going to ask that it be</p> <p>12 read back, please.</p> <p>13 THE WITNESS: Thank you.</p> <p>14 ZOOM PARTICIPANT: Ask her if she remembers it</p> <p>15 and let her answer it. Do you remember the</p> <p>16 question?</p> <p>17 THE WITNESS: I'd like for it to be read back.</p> <p>18 ZOOM PARTICIPANT: Thank you.</p> <p>19 THE WITNESS: Thank you.</p> <p>20 (The requested portion was read back.)</p> <p>21 MR. HANSEL: Object to the form.</p> <p>22 A. The warranty represents their promise or</p> <p>23 assurance that their drug is safe and effective and</p> <p>24 equivalent to the referenced listed drug product; the same</p> <p>25 as the referenced listed drug product.</p>	<p style="text-align: right;">Page 124</p> <p>1 BY MS. ISIDRO:</p> <p>2 Q. But does it form part of what you're relying on</p> <p>3 in making the statement in Paragraph 47 of your report?</p> <p>4 A. It refers -- Footnote 6 refers to P&T committees.</p> <p>5 What manufacturers represent in their ANDA is -- when the</p> <p>6 ANDA's approved, it's -- it means that the manufacturer has</p> <p>7 sufficed and is compliant to receive approval of a</p> <p>8 medication deemed safe and effective.</p> <p>9 Q. Why do you reference -- withdrawn.</p> <p>10 Why did you include Footnote 6 on Paragraph 47?</p> <p>11 A. As a reference for P&T committees.</p> <p>12 Q. And what is the purpose of including that in</p> <p>13 Paragraph 47?</p> <p>14 MR. HANSEL: Objection: Asked and answered.</p> <p>15 A. ASHP or the guidelines that they -- or</p> <p>16 they're -- they're a respected industry organization,</p> <p>17 pharmacy organization that have credible information.</p> <p>18 BY MS. ISIDRO:</p> <p>19 Q. How does the document that is referenced in</p> <p>20 Footnote 6 relate to your statement in Paragraph 47 of your</p> <p>21 report?</p> <p>22 MR. HANSEL: Object to the form. Asked and</p> <p>23 answered, repeatedly.</p> <p>24 A. Again, when a manufacturer's ANDA's approved, it</p> <p>25 represents that they've met all the requirements needed for</p>
<p style="text-align: right;">Page 123</p> <p>1 BY MS. ISIDRO:</p> <p>2 Q. When you use the term warranty in your report, do</p> <p>3 you understand that to be a legal term?</p> <p>4 MR. HANSEL: Object to the form.</p> <p>5 A. No. It's a term that refers to a promise, an</p> <p>6 assurance, a guarantee that that manufacturer has set</p> <p>7 forth.</p> <p>8 BY MS. ISIDRO:</p> <p>9 Q. What are you relying on in making the statements</p> <p>10 that you've made in Paragraph 47 of your report?</p> <p>11 MR. HANSEL: Object to the form.</p> <p>12 A. When an ANDA is approved, it means that the</p> <p>13 manufacturer has fulfilled the requirements, including</p> <p>14 safety and effectiveness, for their drug to be approved.</p> <p>15 BY MS. ISIDRO:</p> <p>16 Q. You reference -- you reference a document in</p> <p>17 Footnote 6 at the end of Paragraph 47?</p> <p>18 A. Uh-huh.</p> <p>19 Q. Is that correct?</p> <p>20 A. Yes.</p> <p>21 Q. Are you relying on that document for purposes of</p> <p>22 the statement that you've made in Paragraph 47 of your</p> <p>23 report?</p> <p>24 MR. HANSEL: Object to the form.</p> <p>25 A. Not exclusively.</p>	<p style="text-align: right;">Page 125</p> <p>1 approval of that drug. That information is public</p> <p>2 information, industry accepted among professionals.</p> <p>3 BY MS. ISIDRO:</p> <p>4 Q. Does the document referenced in Footnote 6</p> <p>5 mention warranties at all?</p> <p>6 MR. HANSEL: Object to the form.</p> <p>7 A. I don't recall.</p> <p>8 BY MS. ISIDRO:</p> <p>9 Q. Okay.</p> <p>10 MS. ISIDRO: Can we mark this as Exhibit 5?</p> <p>11 (Exhibit No. 5 was marked for identification.)</p> <p>12 THE WITNESS: Thank you.</p> <p>13 BY MS. ISIDRO:</p> <p>14 Q. Doctor, you've just been handed Exhibit 5. Is</p> <p>15 that the document that's referenced in Footnote 6?</p> <p>16 A. Yes.</p> <p>17 Q. I'll give you a moment to look it over so that</p> <p>18 you can refresh your recollection as to whether that</p> <p>19 document mentions warranties at all.</p> <p>20 MR. HANSEL: Objection. It takes more than a</p> <p>21 moment to determine whether a 12-paged document with 3</p> <p>22 columns on each page contains a single word at least</p> <p>23 once.</p> <p>24 MS. ISIDRO: I'll give her as much time as she</p> <p>25 needs.</p>

Page 126	Page 128
<p>1 MR. HANSEL: Great.</p> <p>2 THE WITNESS: Okay. What would you like me to</p> <p>3 answer?</p> <p>4 BY MS. ISIDRO:</p> <p>5 Q. Does Exhibit 5 discuss warranties at all?</p> <p>6 A. Exhibit 5 discusses P&T committee's formulary</p> <p>7 systems process for the formulary system, which includes</p> <p>8 safe and effective medications, which safe and effective</p> <p>9 medications are the responsibility of the manufacturer to</p> <p>10 uphold as part of their application process in seeking</p> <p>11 approval, and then for review by a P&T committee and</p> <p>12 consideration for the formulary. Exhibit 5 speaks to all</p> <p>13 of that.</p> <p>14 Q. But it doesn't speak to warranties, does it?</p> <p>15 A. A warranty is the promise that that manufacturer</p> <p>16 makes to -- to the people, to the world that their drug is</p> <p>17 safe and effective. It is by that promise that they</p> <p>18 suffice in doing that, that they obtain approval by the</p> <p>19 FDA.</p> <p>20 Q. Can you show me where Exhibit 5 discusses the</p> <p>21 promise that a manufacturer makes to the world?</p> <p>22 A. If you're looking for those words verbatim, you</p> <p>23 would not find them, but --</p> <p>24 Q. Okay.</p> <p>25 A. -- if you are a clinical person or someone</p>	<p>1 The entire document is a well constructed</p> <p>2 document industry accepted by professionals as capturing</p> <p>3 the process for -- capturing the process for medication</p> <p>4 strategies, approvals, P&T functions, and placement on the</p> <p>5 formulary. It really is -- provides a lot of insight that</p> <p>6 the process is established and followed so that drugs can</p> <p>7 be considered on the formulary if they have obtained FDA</p> <p>8 approval by demonstrating that they are safe and effective</p> <p>9 and it's throughout the document that that can be picked up</p> <p>10 on.</p> <p>11 BY MS. ISIDRO:</p> <p>12 Q. And you cited Exhibit 5 as support for your</p> <p>13 statement in Paragraph 47 of your report, correct?</p> <p>14 A. Yes.</p> <p>15 MR. HANSEL: Take a break?</p> <p>16 MS. ISIDRO: We can go ahead and take a break</p> <p>17 now.</p> <p>18 THE VIDEOGRAPHER: The time is 3:09 p.m., and we</p> <p>19 are going off record.</p> <p>20 (Break taken.)</p> <p>21 THE VIDEOGRAPHER: The time is 3:21 p.m., and we</p> <p>22 are back on the record.</p> <p>23 BY MS. ISIDRO:</p> <p>24 Q. Doctor, in Paragraph 52 of your report, you state</p> <p>25 that manufacturers are responsible for understanding their</p>
Page 127	Page 129
<p>1 familiar with the ASHP or the formulary process, you would</p> <p>2 understand the process around brand and generic drug</p> <p>3 approvals, formulary process, P&T committees, this is what</p> <p>4 we do, and it is industry practice that the drug must meet</p> <p>5 safe and effective -- be in compliance in order to gain</p> <p>6 approval by the FDA. Drugs that are not FDA approved would</p> <p>7 never be part of a drug formulary.</p> <p>8 Q. Okay. And even if not in those specific words, a</p> <p>9 promise that a manufacturer makes to the world, can you</p> <p>10 show me where in Exhibit 5 that concept is discussed?</p> <p>11 A. Page 910 talks about evaluating medications for</p> <p>12 inclusion on the -- in the formulary. That entire section</p> <p>13 refers to the process by which evidence based data should</p> <p>14 be used as part of the process.</p> <p>15 Let me go back over here. The section on P&T</p> <p>16 committee, the section on managing formulary systems, all</p> <p>17 of those sections include the process that is accepted for</p> <p>18 drugs that have -- that can be considered for formulary.</p> <p>19 Q. Okay. Any other sections of Exhibit 5?</p> <p>20 A. There is sections on Page 9 on -- Page 911,</p> <p>21 sorry, generic drugs, formulary exceptions, subformularies,</p> <p>22 therapeutic --</p> <p>23 MR. MESTRE: Are you getting close to a moment</p> <p>24 where you can --</p> <p>25 A. Yeah. I'll just finish this.</p>	<p>1 processes which includes presenting the presence of</p> <p>2 unacceptable -- of unacceptable and impurities.</p> <p>3 A. Right.</p> <p>4 Q. What do you mean by the term impurities in that</p> <p>5 paragraph?</p> <p>6 A. Any substance that does not belong in the</p> <p>7 medication.</p> <p>8 Q. Do you understand -- let me rephrase that.</p> <p>9 As you use them in your report, are the terms</p> <p>10 contaminants and impurities interchangeable?</p> <p>11 A. They --</p> <p>12 MR. HANSEL: Object to the form.</p> <p>13 A. They could be.</p> <p>14 BY MS. ISIDRO:</p> <p>15 Q. But I -- I'd like to know, specifically as you've</p> <p>16 used them in your report, are you using the terms as</p> <p>17 interchangeable?</p> <p>18 A. Impurities or contaminants are items or things</p> <p>19 present that should not be there and potentially dangerous,</p> <p>20 not safe, and not effective.</p> <p>21 Q. In your report are you referring to different</p> <p>22 things when you use the term impurities than when you use</p> <p>23 the term contaminants?</p> <p>24 A. Within the scope of this case and this report</p> <p>25 they can be looked at similar.</p>

<p style="text-align: right;">Page 130</p> <p>1 Q. Is there any distinction to you in your use of</p> <p>2 the term impurities in your report versus your use of the</p> <p>3 term contaminants in your report?</p> <p>4 A. No.</p> <p>5 Q. Do you know whether FDA views the terms</p> <p>6 impurities and contaminants as interchangeable?</p> <p>7 A. I do not know if they view them as</p> <p>8 interchangeable.</p> <p>9 Q. Okay. What is your basis for the statement in</p> <p>10 Paragraph 52 that manufacturers are responsible for</p> <p>11 understanding their processes, which includes preventing</p> <p>12 the presence of unacceptable and impurities?</p> <p>13 A. Manufacturers are the ones submitting their</p> <p>14 application requesting approval; therefore, they are</p> <p>15 responsible for all the information they provide within</p> <p>16 that application.</p> <p>17 Q. And what are you relying on in stating that</p> <p>18 conclusion?</p> <p>19 A. Manufacturers are submitting an ANDA in this --</p> <p>20 in this case. They are requesting that approval. They are</p> <p>21 providing the information.</p> <p>22 Q. So is that your personal opinion based on the</p> <p>23 fact that they're the ones submitting the information?</p> <p>24 A. They are applying for approval, so they must</p> <p>25 adhere to the requirements set forth by the FDA in order to</p>	<p style="text-align: right;">Page 132</p> <p>1 A. That is the industry accepted understanding of</p> <p>2 what -- if a manufacturer is seeking approval of their</p> <p>3 drug, they must file an application with the FDA. In the</p> <p>4 case of a generic drug the application is called an ANDA</p> <p>5 and that is filed with the FDA by the manufacturer who is</p> <p>6 seeking approval of their drug. That application must meet</p> <p>7 the requirements set forth by the FDA to be compliant,</p> <p>8 safe, and effective.</p> <p>9 Q. In Paragraph 55 you state that P&T committees and</p> <p>10 TPPs rely on an Orange Book listing that a manufacturerTMs</p> <p>11 compliance means their drugs meet FDA regulations and as</p> <p>12 such are suitable for formulary placement and reimbursable</p> <p>13 under a prescription drug benefit plan.</p> <p>14 What is the basis for this statement in Paragraph</p> <p>15 55 of your report?</p> <p>16 MR. HANSEL: Object to the form.</p> <p>17 A. My education, experience, and familiarity with</p> <p>18 P&T committees.</p> <p>19 BY MS. ISIDRO:</p> <p>20 Q. Anything else?</p> <p>21 MR. HANSEL: Object to the form.</p> <p>22 A. I've answered the question.</p> <p>23 BY MS. ISIDRO:</p> <p>24 Q. Okay. So that is -- that is the only thing that</p> <p>25 you're relying on making your statement in Paragraph 55 of</p>
<p style="text-align: right;">Page 131</p> <p>1 obtain that approval. So they must provide all of the</p> <p>2 information required. Manufacturers must provide that.</p> <p>3 Q. Must provide all of the information required</p> <p>4 by --</p> <p>5 A. Required for consideration for approval of their</p> <p>6 drug by the FDA, yes.</p> <p>7 Q. And that is what you are relying on in stating --</p> <p>8 let me rephrase.</p> <p>9 And that is what you are relying on in making</p> <p>10 your statement in Paragraph 52?</p> <p>11 A. I'm relying on the fact that manufacturers submit</p> <p>12 applications for drug approval. It's a common, known fact.</p> <p>13 Q. Are you relying on any specific FDA regulations</p> <p>14 in making your statement in Paragraph 52?</p> <p>15 A. I don't understand your question.</p> <p>16 Q. Are there any specific FDA regulations that</p> <p>17 you're relying on in making your statement in Paragraph 52</p> <p>18 of your report?</p> <p>19 A. The FDA regulates that if a manufacturer is</p> <p>20 seeking approval of their drug, they must file -- if it's a</p> <p>21 generic drug, which we're talking about specifically, they</p> <p>22 must file an ANDA application and meet the requirements for</p> <p>23 approval.</p> <p>24 Q. And is that a specific FDA regulation that you're</p> <p>25 referring to or is that your general understanding?</p>	<p style="text-align: right;">Page 133</p> <p>1 your report?</p> <p>2 MR. HANSEL: Object to the form.</p> <p>3 A. As it pertains to generic drugs, yes.</p> <p>4 BY MS. ISIDRO:</p> <p>5 Q. Okay. And as it pertains to brand drugs?</p> <p>6 A. Brand drugs follow another process by the P&T</p> <p>7 committee which is not the scope of this opinion.</p> <p>8 Q. Okay. So does Paragraph 55 refer to anything</p> <p>9 other than generic drugs, any other categories of drugs?</p> <p>10 A. Again, the Orange Book lists drugs that are</p> <p>11 approved in the United States. That's -- also includes</p> <p>12 brand drugs as well as their generic approved drug product.</p> <p>13 So to the extent that I understand your question,</p> <p>14 P&T committees and TPPs will rely on the information in</p> <p>15 part listed in the Orange Book that lists the approved</p> <p>16 medications approved by the FDA for sale in the United</p> <p>17 States or marketing in the United States.</p> <p>18 Q. And are you relying on anything other than your</p> <p>19 education and experience in making that statement?</p> <p>20 MR. HANSEL: Object to the form.</p> <p>21 A. My experience with P&T committees. Again, my</p> <p>22 day-to-day functions are keeping knowledgeable with the</p> <p>23 industry practice, functions, drug information. That's all</p> <p>24 part of what I do so I'm comfortable with what's required</p> <p>25 or what components are essential.</p>

<p style="text-align: right;">Page 134</p> <p>1 BY MS. ISIDRO:</p> <p>2 Q. And that is what you are relying on in making</p> <p>3 your statements in Paragraph 55 of your report and nothing</p> <p>4 else?</p> <p>5 MR. HANSEL: Object to the form.</p> <p>6 A. If we're being specific on a generic drug, the --</p> <p>7 they will -- P&T committees will look to the Orange Book</p> <p>8 for that substitutability rating. Once that rating is --</p> <p>9 once that drug has established that classification, it can</p> <p>10 be considered for the formulary, if it has -- can -- it has</p> <p>11 met FDA approval and it, in terms of generic drugs, is</p> <p>12 really what the reference point is so.</p> <p>13 BY MS. ISIDRO:</p> <p>14 Q. Okay. And -- and what are you basing that answer</p> <p>15 on?</p> <p>16 MR. HANSEL: Object to the form.</p> <p>17 A. Understanding how P&T committees work --</p> <p>18 BY MS. ISIDRO:</p> <p>19 Q. Did --</p> <p>20 A. -- when -- with regards to generic drugs.</p> <p>21 Q. And the basis for that understanding?</p> <p>22 MR. HANSEL: Object to the form.</p> <p>23 A. My experience with P&T committees.</p> <p>24 BY MS. ISIDRO:</p> <p>25 Q. Anything else?</p>	<p style="text-align: right;">Page 136</p> <p>1 including my education and 20 plus years of experience</p> <p>2 within this industry, including familiarity and knowledge</p> <p>3 on P&T committees.</p> <p>4 BY MS. ISIDRO:</p> <p>5 Q. Paragraph 56 again uses the term warranties. Is</p> <p>6 your use of the term warranties in Paragraph 56 referring</p> <p>7 to the same thing that your use of the term warranty of</p> <p>8 Paragraph 47 of your report refers to?</p> <p>9 MR. HANSEL: Object to the form.</p> <p>10 A. Yes. It refers to the same.</p> <p>11 BY MS. ISIDRO:</p> <p>12 Q. Okay. What is the basis for your statement in</p> <p>13 Paragraph 56 of your report?</p> <p>14 MR. HANSEL: Objection to form.</p> <p>15 A. When a drug is placed on the formulary, it's met</p> <p>16 the -- it's met the approval criteria approved by the FDA,</p> <p>17 so it's met that requirement. It can be considered for</p> <p>18 placement on the formulary, and based on that consideration</p> <p>19 or inclusion on the formulary, third-party payors will</p> <p>20 reimburse that on -- for that drug because it is included</p> <p>21 on the formulary because it has met FDA approval for being</p> <p>22 safe and effective.</p> <p>23 BY MS. ISIDRO:</p> <p>24 Q. In Paragraph 57 you state in the case of</p> <p>25 Valsartan, including VCDs warranties by the manufacturers</p>
<p style="text-align: right;">Page 135</p> <p>1 MR. HANSEL: Object to the form.</p> <p>2 A. My education, experience, knowledge.</p> <p>3 BY MS. ISIDRO:</p> <p>4 Q. Any specific documents or regulations?</p> <p>5 A. I've listed all the documents I've reviewed in</p> <p>6 Appendix A.</p> <p>7 Q. Are there any documents listed in Appendix A that</p> <p>8 you're relying on for purposes of the statement that you've</p> <p>9 made in Paragraph 55 of your report?</p> <p>10 A. My entire report is based on all of the data and</p> <p>11 documents in Appendix A and in addition to my education and</p> <p>12 experience so.</p> <p>13 Q. Well, Doctor, I think we've identified specific</p> <p>14 examples of paragraphs within your report that don't rely</p> <p>15 on every document listed in Appendix A, correct?</p> <p>16 MR. HANSEL: Objection. Mischaracterizes</p> <p>17 previous testimony over and over again. Object to the</p> <p>18 form.</p> <p>19 BY MS. ISIDRO:</p> <p>20 Q. You can answer the question.</p> <p>21 MR. HANSEL: Same objection.</p> <p>22 A. Appendix A lists the documents, materials that I</p> <p>23 reviewed in putting together my expert opinion, a report.</p> <p>24 I've reviewed all of those documents and taken them into</p> <p>25 consideration for putting together my expert opinion,</p>	<p style="text-align: right;">Page 137</p> <p>1 were false. What time frame are you referring to in that</p> <p>2 statement?</p> <p>3 A. All of the time frame from which contaminants</p> <p>4 were found in the drug.</p> <p>5 Q. And what was that time frame?</p> <p>6 MR. HANSEL: Object to the form. Foundation.</p> <p>7 Beyond the scope of the report.</p> <p>8 A. The time frame is beyond the scope of this report</p> <p>9 and any of the time that the contaminants were in the drug</p> <p>10 is -- you know, can be considered.</p> <p>11 BY MS. ISIDRO:</p> <p>12 Q. So in -- in formulating your opinions in this</p> <p>13 report, you didn't consider the time frame in which the</p> <p>14 purported contaminants were found; is that correct?</p> <p>15 MR. HANSEL: Object to the form.</p> <p>16 A. I'm not sure I understand your question. Could</p> <p>17 you rephrase that?</p> <p>18 BY MS. ISIDRO:</p> <p>19 Q. I'm just trying to understand your answer that</p> <p>20 the time frame is outside of the scope of the report.</p> <p>21 A. I believe the time frame for the contaminants --</p> <p>22 it's -- the time frame for the contaminants has been</p> <p>23 questioned as to when the original contaminants were there,</p> <p>24 how long they were there, length of time, and so on. So I</p> <p>25 cannot comment on -- on that, other than the fact that</p>

<p style="text-align: right;">Page 138</p> <p>1 there were contaminants within the drug product.</p> <p>2 Q. Do you know when presence of NDMA in Valsartan or</p> <p>3 any VCD was first reported?</p> <p>4 A. When it was first reported? Can you be more</p> <p>5 specific? Reported by whom?</p> <p>6 Q. By anyone.</p> <p>7 A. Again, the time frame on -- I will not speculate</p> <p>8 on -- on that time frame. You're not being specific enough</p> <p>9 when you say anyone.</p> <p>10 Q. When is the first report of NDMA in Valsartan or</p> <p>11 a VCD that you are aware of?</p> <p>12 MR. HANSEL: Object to the form.</p> <p>13 A. In our -- in my professional capacity, we -- the</p> <p>14 FDA had reported the contaminants to the world basically</p> <p>15 so.</p> <p>16 BY MS. ISIDRO:</p> <p>17 Q. When did that occur?</p> <p>18 A. I believe it was 2018 or thereabout. I have</p> <p>19 to -- I'd have to go back and reference the exact date.</p> <p>20 Q. Is that also the first report that you're aware</p> <p>21 of with respect to NDEA in Valsartan or VCDs?</p> <p>22 MR. HANSEL: Object to the form.</p> <p>23 A. Yeah. I can't speculate on those precise dates</p> <p>24 of those -- each of those components. I do know that they</p> <p>25 were present though in the medication.</p>	<p style="text-align: right;">Page 140</p> <p>1 A. Yes.</p> <p>2 Q. Do you know when FDA first set interim limits for</p> <p>3 nitrosamines?</p> <p>4 A. No.</p> <p>5 Q. Do you know when FDA first established guidance</p> <p>6 on control of nitrosamines?</p> <p>7 A. Nope. That was not within the scope of my</p> <p>8 report.</p> <p>9 Q. Okay. In Paragraph 59 of your report you state</p> <p>10 that the presence of the contaminant rendered the</p> <p>11 manufacturer Defendant's versions of VCDs not equivalent to</p> <p>12 the branded product.</p> <p>13 What do you mean by the term contaminant in</p> <p>14 Paragraph 59?</p> <p>15 MR. HANSEL: Object to the form. That doesn't</p> <p>16 read the entire sentence.</p> <p>17 BY MS. ISIDRO:</p> <p>18 Q. Would you prefer if I read the entire sentence,</p> <p>19 Dr. Panagos?</p> <p>20 A. You don't have to.</p> <p>21 Q. Okay. What did you mean by the term contaminant</p> <p>22 in Paragraph 59 of your report?</p> <p>23 A. I referred to item present that should not have</p> <p>24 been present, not consistent with the reference listed drug</p> <p>25 product, and in this case unacceptable levels of a probable</p>
<p style="text-align: right;">Page 139</p> <p>1 BY MS. ISIDRO:</p> <p>2 Q. My question --</p> <p>3 A. I believe the dates are irrelevant.</p> <p>4 Q. Let me clarify my question because my question</p> <p>5 didn't refer to dates and wasn't calling for dates, so let</p> <p>6 me restate my question a different way.</p> <p>7 You referenced a report by FDA to the industry or</p> <p>8 the world with respect to called contaminants in Valsartan</p> <p>9 or in VCDs, correct?</p> <p>10 A. The FDA issued a recall. That's what I mean by</p> <p>11 report. They issued a recall on those drugs.</p> <p>12 Q. Is it your understanding that the recall that you</p> <p>13 reference was initiated by FDA?</p> <p>14 A. The FDA issued the recall. That's what I am</p> <p>15 attesting to. Who initiated the recall, again, what</p> <p>16 matters is the FDA issued the -- the recall.</p> <p>17 Q. What do you mean by the term issued?</p> <p>18 A. They provided the guidance that this recall is</p> <p>19 being set forth.</p> <p>20 Q. What is your understanding -- or what is the</p> <p>21 basis for that statement?</p> <p>22 A. Public information found on the FDA website.</p> <p>23 Q. And the announcement of a recall was -- is that</p> <p>24 the first report that you're aware of with respect to</p> <p>25 presence of NDEA in Valsartan or VCDs?</p>	<p style="text-align: right;">Page 141</p> <p>1 human carcinogen.</p> <p>2 Q. Is there a specific probable human carcinogen</p> <p>3 that you are referring to?</p> <p>4 A. The ones found within the drug that should not</p> <p>5 have been there.</p> <p>6 Q. And which ones were those?</p> <p>7 A. Both of the contaminants that are -- you've</p> <p>8 referenced.</p> <p>9 Q. I'm sorry, I didn't reference any specific</p> <p>10 contaminants in my question.</p> <p>11 A. You asked me about the contaminants in the</p> <p>12 previous question where you asked if I -- something about</p> <p>13 the FDA process around those.</p> <p>14 So to the extent that I understand your question,</p> <p>15 I will answer and say that both of the contaminants in the</p> <p>16 case of these drugs represent a deviation from the</p> <p>17 reference listed drug product and not equivalent.</p> <p>18 Q. Do you remember the names of those two</p> <p>19 contaminants that you're referring to in your response?</p> <p>20 A. They are listed within my report in Section 4,</p> <p>21 Number 12. NDA- -- NDEA and NDMA.</p> <p>22 Q. Okay. In Paragraph 59 of your report -- let me</p> <p>23 rephrase that.</p> <p>24 What is the basis for your opinion that the</p> <p>25 presence of the contaminant rendered the manufacturer</p>

<p style="text-align: right;">Page 142</p> <p>1 Defendant's versions of VCDs not equivalent to the branded</p> <p>2 product?</p> <p>3 A. The contaminants were not in the branded product</p> <p>4 and therefore the generic drug could not have been</p> <p>5 equivalent to the branded product by the presence of the</p> <p>6 contaminants within the product, within the medication.</p> <p>7 Q. In the first half of 2018 do you know whether the</p> <p>8 branded product was being tested for NDMA?</p> <p>9 A. No. That was not within the scope of this</p> <p>10 report.</p> <p>11 Q. In the first half of 2018 do you know whether the</p> <p>12 branded product was being tested for NDEA?</p> <p>13 A. No. That was not within the scope of this</p> <p>14 report.</p> <p>15 Q. At any point prior to 2018 do you know whether</p> <p>16 the branded product was being tested for NDMA?</p> <p>17 A. Same response; not within the scope of this</p> <p>18 report.</p> <p>19 Q. And at any point prior to 2018 do you know</p> <p>20 whether the branded product was being tested for NDEA?</p> <p>21 A. Again, not within the scope of this report.</p> <p>22 Q. Section 6 of your report you provide summary of</p> <p>23 your opinions; is that correct?</p> <p>24 A. Yep.</p> <p>25 Q. And Item B under this summary of opinions again</p>	<p style="text-align: right;">Page 144</p> <p>1 their original ANDA submissions, if you know?</p> <p>2 A. They must be reported to the FDA. Any changes</p> <p>3 must be reported to the FDA, submitted to the FDA.</p> <p>4 Q. In the second part of Statement D under Section 6</p> <p>5 of summary opinions, you state that equivalence is nulled</p> <p>6 and the generic manufacturer may no longer rely on the</p> <p>7 brand name drug label?</p> <p>8 A. Right.</p> <p>9 Q. What is the basis for that statement in Section</p> <p>10 6D of your report?</p> <p>11 A. Uh-huh. The two --</p> <p>12 MR. HANSEL: Object to the form.</p> <p>13 A. The generic drug label no longer is identical or</p> <p>14 matches the -- the brand drug label is -- is inaccurate and</p> <p>15 cannot be deemed equivalent, safe, or effective.</p> <p>16 BY MS. ISIDRO:</p> <p>17 Q. And what is your basis for that statement?</p> <p>18 MR. HANSEL: Object to the form.</p> <p>19 A. For a substitutability to be applied to a</p> <p>20 particular drug, they must demonstrate that they are safe</p> <p>21 and effective. Deviation from that would thereby not</p> <p>22 demonstrate that.</p> <p>23 BY MS. ISIDRO:</p> <p>24 Q. In Statement I under Section 6 you state that the</p> <p>25 warranty from manufacturers for this products -- for these</p>
<p style="text-align: right;">Page 143</p> <p>1 mentions the term warranty. Is the term warranty being</p> <p>2 used in that item 6B in the same way as it is being used in</p> <p>3 Paragraph 47 of your report.</p> <p>4 MR. HANSEL: Object to the form.</p> <p>5 A. Yes.</p> <p>6 BY MS. ISIDRO:</p> <p>7 Q. In Item D under Section 6, you state that the</p> <p>8 generic manufacturer -- that -- excuse me. You state that</p> <p>9 if the generic manufacturer of product changes in any way</p> <p>10 from the original product on the ANDA approval, then this</p> <p>11 changed product is not the same as the brand name</p> <p>12 medication.</p> <p>13 What is your basis for that statement in Item D</p> <p>14 under Section 6 of your report?</p> <p>15 MR. HANSEL: Object to the form.</p> <p>16 A. Any changes to a generic drug product should be</p> <p>17 reported to the FDA. The ANDA in -- in this case or the</p> <p>18 medications in this case with the contaminants inconsistent</p> <p>19 with the ANDA submitted for approval.</p> <p>20 MS. ISIDRO: Can you read back that last sentence</p> <p>21 in the answer? I didn't hear the whole thing. I'm</p> <p>22 sorry.</p> <p>23 (The requested portion was read back.)</p> <p>24 BY MS. ISIDRO:</p> <p>25 Q. Are ANDA holders permitted to make changes to</p>	<p style="text-align: right;">Page 145</p> <p>1 products turned out to false. Is your use --</p> <p>2 A. To be false. Yes.</p> <p>3 Q. So it should say to be false there?</p> <p>4 A. Uh-huh.</p> <p>5 Q. Okay. Is your use of the term warranty here in</p> <p>6 this Statement 6I of your report, are you using that term</p> <p>7 warranty there in the same way -- let me rephrase that</p> <p>8 question.</p> <p>9 Are you using the term warranty in Section 6I of</p> <p>10 your report in the same way that you're using it in</p> <p>11 Paragraph 47 of your report?</p> <p>12 MR. HANSEL: Object to the form.</p> <p>13 A. Yes.</p> <p>14 BY MS. ISIDRO:</p> <p>15 Q. What is your basis for the statement in Paragraph</p> <p>16 6I of your report that the warranty from manufacturers for</p> <p>17 these products turned out to be false?</p> <p>18 MR. HANSEL: Object to the form.</p> <p>19 A. The presence of the contaminants in unacceptable</p> <p>20 levels of probable human carcinogens, misrepresented with</p> <p>21 inaccurate -- did not adhere to the promise they made,</p> <p>22 stating that their drug met the criteria set forth by the</p> <p>23 FDA for approval, which includes that to be that the drug</p> <p>24 is safe and effective and identical to the brand drug --</p> <p>25 reference listed drug.</p>

<p style="text-align: right;">Page 146</p> <p>1 BY MS. ISIDRO:</p> <p>2 Q. You used the phrase unacceptable levels --</p> <p>3 A. Uh-huh.</p> <p>4 Q. -- in your response. What do you mean by</p> <p>5 unacceptable levels?</p> <p>6 A. Unacceptable levels is a -- what the FDA</p> <p>7 referenced in referring to the contaminants, and I will --</p> <p>8 I adhere to the terms that they use.</p> <p>9 Q. And you say what -- what the FDA referenced.</p> <p>10 Where do you mean --</p> <p>11 A. When they --</p> <p>12 Q. -- that the FDA referenced that?</p> <p>13 A. Sorry.</p> <p>14 Q. If you could just let me finish my question.</p> <p>15 Sorry.</p> <p>16 A. Uh-huh.</p> <p>17 Q. Where are you referring to that the FDA</p> <p>18 referenced that?</p> <p>19 A. On their website.</p> <p>20 Q. In what context?</p> <p>21 A. In the context of the recall.</p> <p>22 Q. In the context of the recall. The 2018 recall?</p> <p>23 A. The recall of Valsartan.</p> <p>24 Q. You also state in Paragraph 6I of your report</p> <p>25 that TPPs paid for medications that they should not have</p>	<p style="text-align: right;">Page 148</p> <p>1 Q. Are you aware that FDA has said patients taking</p> <p>2 prescription medications with potential nitrosamine</p> <p>3 impurities should not stop taking their medications?</p> <p>4 MR. HANSEL: Object to the form.</p> <p>5 A. I am aware.</p> <p>6 BY MS. ISIDRO:</p> <p>7 Q. Do you have any knowledge as to the levels of</p> <p>8 NDMA or NDEA that were found in any particular lot of</p> <p>9 Valsartan-containing drugs?</p> <p>10 A. That was not within the scope of this report.</p> <p>11 Q. So, no, you don't have any knowledge as to those</p> <p>12 levels?</p> <p>13 MR. HANSEL: Object to the form.</p> <p>14 A. The specific levels, no.</p> <p>15 BY MS. ISIDRO:</p> <p>16 Q. Do you know whether there were certain lots of</p> <p>17 recalled Valsartan that did not contain any detectable NDMA</p> <p>18 or NDEA?</p> <p>19 MR. HANSEL: Object to the form.</p> <p>20 A. Again, not within the scope of this report. I</p> <p>21 cannot speculate.</p> <p>22 BY MS. ISIDRO:</p> <p>23 Q. Okay. So you don't know one way or the other?</p> <p>24 MR. HANSEL: Object to the form. Assumes facts</p> <p>25 not in evidence.</p>
<p style="text-align: right;">Page 147</p> <p>1 based on the manufacturer's false representation?</p> <p>2 A. That is correct.</p> <p>3 Q. What is your basis for that statement?</p> <p>4 MR. HANSEL: Object to the form.</p> <p>5 A. Medication would not have been approved with the</p> <p>6 contaminant and it would not have been considered for an</p> <p>7 inclusion on a drug formulary and it would not have been</p> <p>8 reimbursed in any way by a TPP if it was not approved.</p> <p>9 BY MS. ISIDRO:</p> <p>10 Q. Okay. Is there anything else that you're basing</p> <p>11 the statement in Paragraph 6I, that TPPs paid for</p> <p>12 medications that they should not have based -- should not</p> <p>13 have based on the manufacturer's false representation?</p> <p>14 MR. HANSEL: Object to the form.</p> <p>15 A. TPPs should not have paid for contaminated</p> <p>16 medication.</p> <p>17 BY MS. ISIDRO:</p> <p>18 Q. What is your basis for that statement?</p> <p>19 MR. HANSEL: Object to the form.</p> <p>20 A. The presence of the contaminants within the</p> <p>21 medications.</p> <p>22 BY MS. ISIDRO:</p> <p>23 Q. Anything else?</p> <p>24 A. My statement I -- is accurate the way it's</p> <p>25 written.</p>	<p style="text-align: right;">Page 149</p> <p>1 A. I would have to review. I cannot speculate to</p> <p>2 that.</p> <p>3 BY MS. ISIDRO:</p> <p>4 Q. So because you're saying you cannot speculate,</p> <p>5 that means you don't know for a fact one way or the other,</p> <p>6 correct?</p> <p>7 MR. HANSEL: Object to the form.</p> <p>8 A. I'm not sure what you mean by one way or another.</p> <p>9 Could you clarify?</p> <p>10 BY MS. ISIDRO:</p> <p>11 Q. Do you know one way or another whether there were</p> <p>12 certain lots of recalled Valsartan that did not contain any</p> <p>13 detectable NDMA or NDEA?</p> <p>14 A. No.</p> <p>15 Q. Dr. Panagos, would you agree that the main</p> <p>16 criterion for the inclusion of any product in the Orange</p> <p>17 Book is that the product is the subject of an application</p> <p>18 with an approval that has not been withdrawn for safety or</p> <p>19 efficacy reasons?</p> <p>20 A. Current approval, yes.</p> <p>21 Q. And you would agree that FDA determines</p> <p>22 bioequivalence, correct?</p> <p>23 A. It's one of the factors that they look for when</p> <p>24 evaluating drug applications.</p> <p>25 Q. In order to -- in order for a prescription drug</p>

<p style="text-align: right;">Page 150</p> <p>1 product to be considered bioequivalent to another drug</p> <p>2 product, FDA has to make that determination, correct?</p> <p>3 A. It's part of the --</p> <p>4 MR. HANSEL: Objection to form.</p> <p>5 A. It's part of their consideration.</p> <p>6 BY MS. ISIDRO:</p> <p>7 Q. Is there any other entity that is tasked with</p> <p>8 determining bioequivalence for prescription drug products</p> <p>9 in the United States besides FDA?</p> <p>10 A. Not to my knowledge.</p> <p>11 Q. And FDA's determination as to bioequivalence is</p> <p>12 made individually for each manufacturer and each product,</p> <p>13 correct?</p> <p>14 A. For each submitted application, each ANDA is</p> <p>15 evaluated individually.</p> <p>16 Q. Okay. FDA may change a product's therapeutic</p> <p>17 equivalence rating if the circumstances giving rise to a</p> <p>18 violation call into question the agency's assessment of</p> <p>19 whether a product meets the criteria for therapeutic</p> <p>20 equivalence, correct?</p> <p>21 A. Yes.</p> <p>22 Q. During the time frame that -- let me rephrase</p> <p>23 that.</p> <p>24 Prior to the Valsartan recall in 2018, FDA did</p> <p>25 not take any steps that would reflect a determination that</p>	<p style="text-align: right;">Page 152</p> <p>1 was important to me to know what their strategy was going</p> <p>2 to be.</p> <p>3 Q. In coming up with your opinions in this</p> <p>4 litigation, did you consult with any P&T committees about</p> <p>5 the inclusion of Valsartan on a formulary?</p> <p>6 A. No.</p> <p>7 Q. And in coming up with your opinions in this</p> <p>8 litigation, did you consult with any P&T committee about</p> <p>9 its use of the Orange Book?</p> <p>10 A. No. Because I -- I know that's what they use.</p> <p>11 Q. And in coming up with your opinions in this</p> <p>12 litigation, did you consult with any TPPs about the</p> <p>13 inclusion of Valsartan on a formulary?</p> <p>14 A. No.</p> <p>15 Q. In coming up with your opinions in this</p> <p>16 litigation did you consult with any TPP about its use of</p> <p>17 the Orange Book?</p> <p>18 MR. HANSEL: Object to form.</p> <p>19 A. Let me clarify that TPPs and committees, it is</p> <p>20 industry practice that they refer to the authoritative</p> <p>21 source known as the Orange Book for substitutability, for a</p> <p>22 list of drugs that are approved by the FDA marketed in the</p> <p>23 United States.</p> <p>24 This is an ongoing, continual process, and in my</p> <p>25 day-to-day functions in my role as a clinical pharmacist</p>
<p style="text-align: right;">Page 151</p> <p>1 the products were no longer therapeutically equivalent,</p> <p>2 correct?</p> <p>3 A. Not to my knowledge.</p> <p>4 Q. You didn't review bioequivalence studies for any</p> <p>5 manufacturer Defendant's Valsartan-containing products, did</p> <p>6 you?</p> <p>7 A. No.</p> <p>8 Q. Did you consult with any actual P&T committees</p> <p>9 about the inclusion of Valsartan on a formulary?</p> <p>10 A. Could you be more specific?</p> <p>11 Q. How do you mean?</p> <p>12 A. Valsartan is a generic drug.</p> <p>13 Q. Uh-huh.</p> <p>14 A. It would meet criteria for inclusion on the</p> <p>15 formulary if it is approved by the FDA following an ANDA</p> <p>16 application that meets the criteria for approval set forth</p> <p>17 by the FDA which -- including safety and effectiveness.</p> <p>18 Q. Have you personally consulted with any actual P&T</p> <p>19 committees about the inclusion of Valsartan on a formulary?</p> <p>20 A. I'm going to ask you to specify on time frame.</p> <p>21 Q. Ever.</p> <p>22 A. Following the recall it is -- the -- P&T</p> <p>23 committees had to kind of create a strategy around how to</p> <p>24 move forward with that information as it pertains to their</p> <p>25 drug formularies, and on behalf of my clients I was -- it</p>	<p style="text-align: right;">Page 153</p> <p>1 and a consultant, those are the responsibilities that are</p> <p>2 consistent in industry and what are adhered -- are adhered</p> <p>3 to.</p> <p>4 BY MS. ISIDRO:</p> <p>5 Q. In formulating your opinions in this litigation,</p> <p>6 did you consult with any TPP about its use of the Orange</p> <p>7 Book?</p> <p>8 A. The use of the Orange Book is an established</p> <p>9 process that is widely accepted and respected. It is the</p> <p>10 source of truth in terms of approved products, approved by</p> <p>11 the FDA and substitutable. It is the source of truth. It</p> <p>12 is relied upon by P&T committees for their generic</p> <p>13 medications to be considered for inclusion on the</p> <p>14 formulary. That does not change.</p> <p>15 Q. Dr. Panagos, at this time I'm not asking you</p> <p>16 about the basis of your opinions with respect to a TPP's</p> <p>17 use of the Orange Book in general. I am asking you</p> <p>18 whether, in formulating your opinions in this litigation,</p> <p>19 did you consult with any TPP about its use of the Orange</p> <p>20 Book?</p> <p>21 A. No, I did not need to consult with them because</p> <p>22 I'm confident that is the process that is adhered to.</p> <p>23 Q. Let's -- let's go ahead and take a break.</p> <p>24 THE VIDEOGRAPHER: It's 4:10 p.m., and we're</p> <p>25 going off the record.</p>

Page 154	Page 156
<p>1 (Break taken.)</p> <p>2 THE VIDEOGRAPHER: It is 4:34 p.m., and we are</p> <p>3 back on the record.</p> <p>4 MS. ISIDRO: Dr. Panagos, I may have some further</p> <p>5 follow-up for you at -- in a little bit, but I don't</p> <p>6 have any further questions for you right now.</p> <p>7 As I mentioned previously, there are some folks</p> <p>8 on Zoom and I'm not sure whether any of them have any</p> <p>9 questions for you right now.</p> <p>10 MR. GISLESON: Actually, I do have a few</p> <p>11 questions. Can you hear me?</p> <p>12 MR. KERNER: We can.</p> <p>13 THE WITNESS: Yes.</p> <p>14 CROSS-EXAMINATION</p> <p>15 BY MR. GISLESON:</p> <p>16 Q. Hey, Doctor. My name is John Gisleson. I</p> <p>17 represent a manufacturer named Aurobindo. Have you heard</p> <p>18 of Aurobindo before?</p> <p>19 A. Yes.</p> <p>20 Q. And are you aware that Aurobindo is a</p> <p>21 manufacturer of Valsartan and Valsartan-containing drugs?</p> <p>22 A. Yes, I'm aware.</p> <p>23 Q. Did you become aware of any public information</p> <p>24 that certain batches of Aurobindo Valsartan or</p> <p>25 Valsartan-containing drugs contained nitrosamine?</p>	<p>1 MR. HANSEL: Excuse me. Excuse me, Mr. Gisleson?</p> <p>2 MR. GISLESON: Yes?</p> <p>3 MR. HANSEL: Please let Dr. Panagos finish her</p> <p>4 answer. This is the second --</p> <p>5 MR. GISLESON: I'm sorry. I thought she was</p> <p>6 finished.</p> <p>7 MR. HANSEL: This is the second time you've</p> <p>8 interrupted her and perhaps there's a lag. So please</p> <p>9 give her a moment to make sure -- sometimes she thinks</p> <p>10 about her answer carefully before she's finished.</p> <p>11 Thank you.</p> <p>12 MR. GISLESON: That's helpful. Thanks for</p> <p>13 letting me know.</p> <p>14 BY MR. GISLESON:</p> <p>15 Q. I'm sorry, you can continue.</p> <p>16 A. I just want to make -- go back the original</p> <p>17 question.</p> <p>18 THE WITNESS: Could you please restate his</p> <p>19 original question?</p> <p>20 MR. HANSEL: And could you please restate her</p> <p>21 partial answer. Thank you.</p> <p>22 (The requested portion was read back.)</p> <p>23 A. Okay. So any time there is a contaminant or</p> <p>24 there is an issue with a medication, it is my</p> <p>25 responsibility to understand that as it pertains to the</p>
Page 155	Page 157
<p>1 A. I was aware that there were contaminants within</p> <p>2 Valsartan products.</p> <p>3 Q. Did you learn what those contaminants were?</p> <p>4 A. The contaminants are referenced within my report,</p> <p>5 Section 4 --</p> <p>6 Q. What was the name of the contaminants?</p> <p>7 A. -- Page -- Section 4, excuse me, Page 2, Number</p> <p>8 12, NDEA and NDMA.</p> <p>9 Q. Before this lawsuit and you were hired as an</p> <p>10 expert, had you ever heard the word nitrosamine before?</p> <p>11 A. Yes.</p> <p>12 Q. In what context?</p> <p>13 A. I am a New York State licensed pharmacist,</p> <p>14 clinical pharmacist, and in my role, my day-to-day</p> <p>15 functions, it is my responsibility to understand</p> <p>16 medications -- FDA medications, approved medications, and</p> <p>17 any concerns surrounding those medications is part of my</p> <p>18 responsibility.</p> <p>19 Q. And how did you learn what nitrosamine are?</p> <p>20 A. There is a component of toxicology that is</p> <p>21 included in our pharmacy education; however, that was --</p> <p>22 that is not within the scope of my report or the opinion</p> <p>23 that I'm rendering here.</p> <p>24 With regards --</p> <p>25 Q. Do you know how nitrosamine perform --</p>	<p>1 scope of my work and my responsibilities as a pharmacist</p> <p>2 and as a prescription -- a pharmacy benefit consultant.</p> <p>3 And so with regards to the generic drugs in this case,</p> <p>4 those contaminants should not have been there.</p> <p>5 BY MR. GISLESON:</p> <p>6 Q. When did you learn of the presence of</p> <p>7 nitrosamines in Valsartan-containing drugs?</p> <p>8 A. When the FDA issued the recall.</p> <p>9 Q. Do you know whether that became publicized in the</p> <p>10 third-party payor and PBM industries about the recall or</p> <p>11 voluntary recall of Valsartan-containing drugs?</p> <p>12 A. Yes.</p> <p>13 Q. Did you speak with different individuals in the</p> <p>14 industry about the recall?</p> <p>15 A. Yes. As it pertains to my clients.</p> <p>16 Q. Did you, personally, recommend that any of your</p> <p>17 clients remove a Valsartan-containing drug from their</p> <p>18 formulary because it was reported to have the presence of</p> <p>19 nitrosamines?</p> <p>20 MR. HANSEL: Objection. This gets into a number</p> <p>21 of areas that I want to comment on. This is</p> <p>22 confidential and Dr. Panagos appears today in her</p> <p>23 capacity as an expert witness, not in her capacity as</p> <p>24 a senior vice president or executive vice president of</p> <p>25 ARMSRx, and to ask her about her advice to her</p>

<p style="text-align: right;">Page 158</p> <p>1 confidential clients is outside the permitted scope of</p> <p>2 this examination.</p> <p>3 BY MR. GISLESON:</p> <p>4 Q. Can you identify any of the clients for whom you</p> <p>5 work pertaining to formulary issues?</p> <p>6 A. I don't think I understand your question.</p> <p>7 Do you want me to --</p> <p>8 Q. Do you consider all of your clients to be</p> <p>9 confidential?</p> <p>10 A. Yes, I do.</p> <p>11 Q. Is it correct that you can't identify then any</p> <p>12 client for whom you have done work concerning a formulary</p> <p>13 because you consider all of your clients to be</p> <p>14 confidential?</p> <p>15 A. You have to rephrase that question. It did not</p> <p>16 make sense.</p> <p>17 Q. Do you consider every single one of the clients</p> <p>18 for whom you have provided counseling on formulary issues</p> <p>19 to be confidential?</p> <p>20 A. My clients that I provide consulting on, that</p> <p>21 information is confidential, but if you're -- so I'm not</p> <p>22 sure what you're asking exactly.</p> <p>23 Q. Are there any clients that you can identify for</p> <p>24 whom you have provided consultation or advice concerning</p> <p>25 inclusion of drugs in a formulary?</p>	<p style="text-align: right;">Page 160</p> <p>1 A. That information is confidential and does --</p> <p>2 isn't pertinent to -- or within the scope of this opinion.</p> <p>3 BY MR. GISLESON:</p> <p>4 Q. So you are -- are refusing to identify the names</p> <p>5 of any third-party payors in any prescription benefit</p> <p>6 management companies for whom you have done work; is that</p> <p>7 correct?</p> <p>8 MR. HANSEL: Object to the form. It's not a</p> <p>9 refusal. She is bound by client confidentiality, so</p> <p>10 she is complying with her obligation to maintain</p> <p>11 client confidentiality.</p> <p>12 She's not refusing to do anything, Counselor.</p> <p>13 BY MR. GISLESON:</p> <p>14 Q. You will not answer or identify the names of any</p> <p>15 of the TPPs or PBMs for whom you have done work because, in</p> <p>16 your view, you're bound by confidentiality agreements that</p> <p>17 prohibit you from identifying the names of those companies;</p> <p>18 is that right?</p> <p>19 A. Yes. And I will respect those.</p> <p>20 Q. Now, since the time that it became public that</p> <p>21 certain manufacturers of Valsartan-containing drugs found</p> <p>22 the presence of nitrosamines in certain batches of their</p> <p>23 products, are you aware of any TPP anywhere in the country</p> <p>24 that removed a drug manufacturer from its formulary based</p> <p>25 on recall?</p>
<p style="text-align: right;">Page 159</p> <p>1 MR. HANSEL: Object to the form. Do you mean</p> <p>2 identify in her mind or --</p> <p>3 MR. GISLESON: The names.</p> <p>4 MR. HANSEL: -- or testify to because they're</p> <p>5 confidential -- you know, because they're not</p> <p>6 confidential?</p> <p>7 MR. GISLESON: Correct.</p> <p>8 BY MR. GISLESON:</p> <p>9 Q. Are there any that you can identify that you do</p> <p>10 not consider to be confidential so that we can have an idea</p> <p>11 of the kinds of companies that you have counseled on</p> <p>12 formulary issues?</p> <p>13 MR. HANSEL: Just on the confidentiality issue,</p> <p>14 she can testify about the kinds of companies.</p> <p>15 BY MR. GISLESON:</p> <p>16 Q. Can you identify any third-party payor for who</p> <p>17 you have -- for whom you have performed work?</p> <p>18 MR. HANSEL: Object to the form.</p> <p>19 A. My clients include self-insured employers,</p> <p>20 third-party payers. I've -- I've indicated those within my</p> <p>21 expert report.</p> <p>22 BY MR. GISLESON:</p> <p>23 Q. Can you identify any of them by name?</p> <p>24 MR. HANSEL: Objection. Asked and answered.</p> <p>25 Confidential.</p>	<p style="text-align: right;">Page 161</p> <p>1 MR. HANSEL: Object to the form.</p> <p>2 A. Based on the recall there were strategies put</p> <p>3 into place, thoughtful, careful strategies put into place</p> <p>4 with guidance from the FDA.</p> <p>5 BY MR. GISLESON:</p> <p>6 Q. Strategies to do what?</p> <p>7 A. How to best manage the recall as it pertains to</p> <p>8 patients who were taking those drugs and the best way</p> <p>9 for -- you know, to handle that.</p> <p>10 Q. Can you identify any TPP anywhere in the country</p> <p>11 that removed one of the Defendant's VCDs from their</p> <p>12 formulary because of the recall?</p> <p>13 A. In which time frame?</p> <p>14 Q. At any point after the recall was publicized.</p> <p>15 A. That was not within the scope of this report.</p> <p>16 Again, strategies were put into place to efficiently manage</p> <p>17 the recall, ensure that patients are not hurt by that.</p> <p>18 Q. Right. But this goes to your opinion that the</p> <p>19 manufacturer warranty for these VCDs was false. TPPs</p> <p>20 unjustly paid for medications for which they have not have</p> <p>21 paid.</p> <p>22 A. Right.</p> <p>23 Q. My question is: Can you identify any TPP</p> <p>24 anywhere in the country, in the United States, that removed</p> <p>25 one of the Defendant's products from its formulary</p>

<p style="text-align: right;">Page 162</p> <p>1 following the recall?</p> <p>2 A. Following the recall, there were strategies put</p> <p>3 in place that included those particular NDCs no longer</p> <p>4 being a part of the formulary.</p> <p>5 Q. Were they removed formally from the formularies?</p> <p>6 A. I cannot speculate. They -- they were just</p> <p>7 not -- they were blocked.</p> <p>8 Q. Okay. So the question's specific. Can you</p> <p>9 identify any TPP anywhere in the country that, in fact,</p> <p>10 removed a manufacturer's VCD from its formulary following</p> <p>11 the recall?</p> <p>12 A. I will go back and say that TPPs or PBMs blocked</p> <p>13 the -- the drugs that were contaminated. That time frame</p> <p>14 is some point after the recall, after sufficient or</p> <p>15 adequate strategy was put through to -- based on the</p> <p>16 recommendations and guidance of the FDA.</p> <p>17 Q. What do you mean by blocked?</p> <p>18 A. The claims were no longer being adjudicated.</p> <p>19 Q. What do you mean by no longer adjudicated?</p> <p>20 A. If a patient went to the pharmacy with an NDC --</p> <p>21 with a drug that had an NDC -- for a drug that had an NDC</p> <p>22 that was a contaminated product, those NDCs would not</p> <p>23 process -- they would not process on the claim's</p> <p>24 adjudication so that -- because they were contaminated.</p> <p>25 Q. So because the VCDs were blocked, at that point</p>	<p style="text-align: right;">Page 164</p> <p>1 VCD that had the presence of nitrosamine?</p> <p>2 A. If a TPP had the generic drug on their formulary</p> <p>3 during the time frame for which the contaminants were</p> <p>4 found, they, in that entirety of that time frame, they</p> <p>5 essentially paid for something they should not have.</p> <p>6 Q. Can you identify any TPP anywhere in the United</p> <p>7 States that sought a refund from a manufacturer as a result</p> <p>8 of a beneficiary consuming a VCD that contained a</p> <p>9 nitrosamine?</p> <p>10 A. That's not within the scope of my report or</p> <p>11 opinion I've been asked to render.</p> <p>12 Q. Can you identify any such TPP or PBM anywhere in</p> <p>13 the country who sought a refund because a patient consumed</p> <p>14 a VCD that had the presence of nitrosamine?</p> <p>15 A. What do you mean by a refund?</p> <p>16 Q. Said that they paid for a VCD for one of their</p> <p>17 beneficiaries and should not have because it contained</p> <p>18 nitrosamine?</p> <p>19 MR. HANSEL: Objection. Calls for a legal</p> <p>20 conclusion.</p> <p>21 A. I'll go back and say that TPPs paid for a drug</p> <p>22 that was placed on the formulary because it had sufficed</p> <p>23 the criteria for approval as set forth by the FDA, and, as</p> <p>24 such, paid for the claims for those drugs where they should</p> <p>25 not have.</p>
<p style="text-align: right;">Page 163</p> <p>1 the TPP did not pay for any of the VCDs at that point?</p> <p>2 Strike that.</p> <p>3 Because the NDC for the BDC was blocked, did that</p> <p>4 mean that the TPP did not pay for a prescription for that</p> <p>5 patient?</p> <p>6 A. I cannot speculate and that was not within the</p> <p>7 scope of this report or the opinion that I'm rendering here</p> <p>8 today. I do know that the TPPs paid for contaminated</p> <p>9 products where they should not have because they were not</p> <p>10 safe and effective.</p> <p>11 At -- after the FDA issued the recall, there had</p> <p>12 to be a careful, thoughtful strategy, there was guidance,</p> <p>13 and so I can't say with certainty that they didn't continue</p> <p>14 to pay for those claims.</p> <p>15 Q. Well, based on your industry expertise, can you</p> <p>16 identify any TPP who, in fact, paid for a VCD that had the</p> <p>17 presence of nitrosamine?</p> <p>18 MR. HANSEL: Object to the form. Beyond the</p> <p>19 scope of the report. Asked and answered.</p> <p>20 BY MR. GISLESON:</p> <p>21 Q. You can answer.</p> <p>22 A. As part of my day-to-day responsibilities, I</p> <p>23 review claims data that consists of medications and --</p> <p>24 including possibly these medications with the contaminants.</p> <p>25 Q. Can you identify by name any TPP that paid for a</p>	<p style="text-align: right;">Page 165</p> <p>1 BY MR. GISLESON:</p> <p>2 Q. Well, you say they shouldn't have, but my</p> <p>3 question is are you aware of any TPP anywhere in the United</p> <p>4 States that sought to be reimbursed from a manufacturer</p> <p>5 because the manufacturer's VCD contained nitrosamine?</p> <p>6 MR. HANSEL: Objection: Calls for a legal</p> <p>7 conclusion.</p> <p>8 A. It is my understanding that TPPs are -- were,</p> <p>9 from the economic standpoint, negatively affected by</p> <p>10 these -- payment of these drugs.</p> <p>11 BY MR. GISLESON:</p> <p>12 Q. Understanding. How?</p> <p>13 A. They paid for the drugs during the time period</p> <p>14 for which they should not have because they were</p> <p>15 contaminated. That information is found within claims</p> <p>16 data.</p> <p>17 Q. Can you identify a single TPP that sought a</p> <p>18 refund prior to this lawsuit being filed because it paid</p> <p>19 for a VCD consumed by a beneficiary that contained</p> <p>20 nitrosamine? And if you can't, that's fine. I'm just</p> <p>21 asking based on your industry experience and contacts if</p> <p>22 you're aware of any TPP that sought a refund.</p> <p>23 A. I believe that information is within the</p> <p>24 complaint.</p> <p>25 Q. And that's the only basis for that information</p>

Page 166	Page 168
<p>1 that you have? None from your own personal experience?</p> <p>2 A. That is correct.</p> <p>3 Q. Now, you said that once the recall was announced,</p> <p>4 it was necessary for TPPs to manage how to respond to the</p> <p>5 recall; is that right?</p> <p>6 A. They needed to understand the recall and then</p> <p>7 determine a strategy.</p> <p>8 Q. Did you have an understanding as to what the</p> <p>9 strategies were that were implemented by TPPs as a result</p> <p>10 of the recall?</p> <p>11 A. Based on FDA guidance.</p> <p>12 Q. What do you mean?</p> <p>13 A. The recommendations that FDA made as a response</p> <p>14 to the recall and the concern about the safety of the drug</p> <p>15 and how to handle that.</p> <p>16 Q. Did you become aware that the FDA issued</p> <p>17 acceptable intake levels?</p> <p>18 MR. HANSEL: Objection. Beyond the scope.</p> <p>19 Object to the form.</p> <p>20 BY MR. GISLESON:</p> <p>21 Q. You can answer.</p> <p>22 A. The FDA commented that the recall was attributed</p> <p>23 to unacceptable levels of a probable human carcinogen</p> <p>24 within the medication.</p> <p>25 Q. In your experience, did the third-party payors</p>	<p>1 A. No.</p> <p>2 Q. So following the recall, is it more than --</p> <p>3 strike that.</p> <p>4 Is it more than five TPPs with whom you've had</p> <p>5 contact since the recall of -- of VCDs?</p> <p>6 A. Again, my clients can include TPPs, self-insured</p> <p>7 employer groups. So I've been in contact -- I was in</p> <p>8 contact with all of them. I think the number is</p> <p>9 irrelevant.</p> <p>10 Q. In your experience, you certainly advise all</p> <p>11 those different clients that there were acceptable intake</p> <p>12 levels for VCDs containing nitrosamines, right?</p> <p>13 MR. HANSEL: Object to the form.</p> <p>14 A. I advised the clients what the FDA set forth in</p> <p>15 terms of the recall, the strategy, their recommendation,</p> <p>16 and guidance.</p> <p>17 BY MR. GISLESON:</p> <p>18 Q. So understood then that for VCDs that</p> <p>19 contained nitrosamines within the acceptable intake level,</p> <p>20 that patients could continue to consume those VCDs,</p> <p>21 correct?</p> <p>22 MR. HANSEL: Object to the form.</p> <p>23 A. Those -- that drug is taken for cardiovascular</p> <p>24 issues, hypertension. A very serious health condition, one</p> <p>25 for which a patient has to be closely followed, monitored</p>
Page 167	Page 169
<p>1 and the PBMs become aware that there were acceptable intake</p> <p>2 levels of nitrosamine impurities in Valsartan and</p> <p>3 Valsartan-containing drugs?</p> <p>4 MR. HANSEL: Object to the form. Foundation.</p> <p>5 Object to the foundation.</p> <p>6 A. Are you --</p> <p>7 BY MR. GISLESON:</p> <p>8 Q. Let me start over.</p> <p>9 You communicate with TPPs, right?</p> <p>10 A. Yes.</p> <p>11 Q. And on and after the recall of</p> <p>12 Valsartan-containing drugs, you communicated with TPPs; is</p> <p>13 that correct?</p> <p>14 A. Yes.</p> <p>15 Q. Approximately how many different TPPs have you</p> <p>16 communicated with following the recall of the -- of the</p> <p>17 VCDs?</p> <p>18 A. Not sure.</p> <p>19 Q. Can you approximate in any way?</p> <p>20 A. I do not wish to do that.</p> <p>21 Q. Being conservative, is it more than a hundred?</p> <p>22 A. No.</p> <p>23 Q. Is it more than fifty?</p> <p>24 A. No.</p> <p>25 Q. Is it more than ten?</p>	<p>1 by their prescriber, and it is never advisable to abruptly</p> <p>2 stop a medication like that because of the critical nature</p> <p>3 for which it's used.</p> <p>4 How to carefully mitigate the recall and the</p> <p>5 issues surrounding the recall at the time were of --</p> <p>6 paramount of importance to my clients, and that's what I</p> <p>7 did.</p> <p>8 BY MR. GISLESON:</p> <p>9 Q. So what you're saying is that TPPs wanted to</p> <p>10 ensure the health and safety of their beneficiaries who</p> <p>11 needed to take VCDs, right?</p> <p>12 MR. HANSEL: Objection. Mr. Gisleson, I'm going</p> <p>13 to cut off this line of questioning.</p> <p>14 I object to the form. It is outside the scope of</p> <p>15 her report. You have asked about this issue 12</p> <p>16 different Ways. The witness has attempted to be</p> <p>17 cooperative, even though testifying that it is outside</p> <p>18 the scope of her report.</p> <p>19 The report does not get into this. You're asking</p> <p>20 about her professional activities for a company that</p> <p>21 is not the expert in this case. Dr. Panagos is</p> <p>22 appearing individually, not on behalf of her employer</p> <p>23 for whom she did that work. The work is also</p> <p>24 confidential. So we're going to need to move on to</p> <p>25 another topic.</p>

<p style="text-align: right;">Page 170</p> <p>1 BY MR. GISLESON:</p> <p>2 Q. You said that the manufacturer warranty for these</p> <p>3 VCDs was false. TPPs unjustly paid for medications for</p> <p>4 which they should not have paid. Based on your serving as</p> <p>5 an expert in this case, are you aware that there were TPPs</p> <p>6 who paid for medications containing nitrosamines because</p> <p>7 the patients needed those medications for health reasons?</p> <p>8 A. I understand that there -- in the strategy, that</p> <p>9 some strategies that took place were advising patients</p> <p>10 never to abruptly stop their medication and to consult with</p> <p>11 their prescriber as to a suitable transition.</p> <p>12 Q. Did different patients have different transition</p> <p>13 periods?</p> <p>14 MR. HANSEL: Excuse me. Mr. Gisleson, I have</p> <p>15 really tried to accommodate your questioning. I know</p> <p>16 you're trying to tie it to the report. Asking about</p> <p>17 patients of her clients now is unacceptable.</p> <p>18 MR. GISLESON: I'm not asking about her client's</p> <p>19 patients.</p> <p>20 MR. HANSEL: Well, I'm going to instruct the</p> <p>21 witness not to answer any questions about the patients</p> <p>22 of her clients of ARMSRx, which is not the testifying</p> <p>23 entity here.</p> <p>24 Do not answer any questions about patients of</p> <p>25 ARMSRx clients.</p>	<p style="text-align: right;">Page 172</p> <p>1 bioequivalent drug products.</p> <p>2 BY MR. GISLESON:</p> <p>3 Q. You looked at that definition before preparing</p> <p>4 your report?</p> <p>5 MR. HANSEL: Object to the form. It's in the</p> <p>6 report.</p> <p>7 A. I'm not --</p> <p>8 BY MR. GISLESON:</p> <p>9 Q. Did you ever have occasion before being retained</p> <p>10 as an expert in this case to look at the FDA definition of</p> <p>11 bioequivalence?</p> <p>12 A. It's part of the scope of my profession.</p> <p>13 Q. Pardon me?</p> <p>14 A. It's within the scope of my profession as a</p> <p>15 pharmacist that bioequivalent is within that knowledge</p> <p>16 base.</p> <p>17 Q. Right. But did you read the FDA definition of</p> <p>18 bioequivalence at any point before you became retained as</p> <p>19 an expert in this lawsuit?</p> <p>20 A. Possibly. I read many, many data, information,</p> <p>21 articles, studies, part of what I do day-to-day. I mean.</p> <p>22 Q. Do you have any personal experience with the</p> <p>23 manufacturing of pharmaceutical products?</p> <p>24 A. No.</p> <p>25 Q. You said in your report at Paragraph 46 TPPs and</p>
<p style="text-align: right;">Page 171</p> <p>1 BY MR. GISLESON:</p> <p>2 Q. Well, Doctor, do you know anything about TPPs and</p> <p>3 how they managed for the recall who are not your clients?</p> <p>4 A. In general TPPs were managing the recall in a --</p> <p>5 in a way that would allow access. As I said before, we --</p> <p>6 not -- access, ensuring that patients can have time frame</p> <p>7 to transition to a non-contaminated product.</p> <p>8 Q. Over what time period did that transition occur,</p> <p>9 to your knowledge?</p> <p>10 A. That's not within the scope of my report and</p> <p>11 that -- that's very patient specific information on how and</p> <p>12 when a patient consults with their prescriber and</p> <p>13 pharmacist in their individual case on how to transition to</p> <p>14 a non-contaminated FDA approved product.</p> <p>15 Q. Do you know what the FDA definition of</p> <p>16 bioequivalence is?</p> <p>17 MR. HANSEL: Objection. Asked and answered.</p> <p>18 This was gone over in great detail by Attorney Isidro.</p> <p>19 MR. GISLESON: I don't think we got a clear</p> <p>20 answer to it.</p> <p>21 BY MR. GISLESON:</p> <p>22 Q. Do you know what the FDA definition is of</p> <p>23 bioequivalence?</p> <p>24 MR. HANSEL: Object to the form.</p> <p>25 A. Page 6, Section E under 33 has the definition for</p>	<p style="text-align: right;">Page 173</p> <p>1 P&T committees expressly rely upon the manufacturers</p> <p>2 compliance with all applicable standards, obligations, and</p> <p>3 regulations. What actions, in your experience, do TPPs</p> <p>4 take to determine whether manufacturer's complied with</p> <p>5 applicable standards, obligations, and regulations?</p> <p>6 A. They reference the Orange Book, that if a drug is</p> <p>7 listed in the Orange Book, it means that it has been</p> <p>8 assigned FDA approval, been given FDA approval, which means</p> <p>9 that they had sufficed -- fulfilled the requirements of the</p> <p>10 ANDA, which includes that their drug is safe and effective.</p> <p>11 Q. Anything else?</p> <p>12 A. If we're referring to generic drugs, this is the</p> <p>13 authoritative source.</p> <p>14 Q. When did TPPs begin to implement a block on VCDs</p> <p>15 based on the recall?</p> <p>16 MR. HANSEL: Objection. This is beyond the scope</p> <p>17 of her report. I permitted some questions about this.</p> <p>18 I believe you've beaten that horse pretty thoroughly.</p> <p>19 It's not part of her report, she's not being proffered</p> <p>20 as an expert on that issue, and I would just ask you</p> <p>21 to please move on.</p> <p>22 MR. GISLESON: No. I haven't beaten this horse.</p> <p>23 I'm still riding it and it's still healthy and in good</p> <p>24 shape. This goes directly to her opinion that TPPs</p> <p>25 unjustly paid for medications which they should not</p>

<p style="text-align: right;">Page 174</p> <p>1 have paid; if there was a block, they didn't pay.</p> <p>2 BY MR. GISLESON:</p> <p>3 Q. So do you have an understanding as to what period</p> <p>4 of time TPPs implemented blocks concerning VCDs that were</p> <p>5 found to have the presence of nitrosamines?</p> <p>6 MR. HANSEL: Object to the form.</p> <p>7 A. The strategy that TPPs put in place following the</p> <p>8 recall is not a universal strategy across all TPPs and how</p> <p>9 they did that and when they did that is very much within</p> <p>10 that entity and was -- is not within the scope of my</p> <p>11 report, nor what -- what I was asked to render an opinion</p> <p>12 on.</p> <p>13 What I do attest to is that TPPs paid for the</p> <p>14 drugs that were contaminated, would not have been FDA</p> <p>15 approved with the contaminant because they would not have</p> <p>16 been the same as the referenced labeled drug. So it's</p> <p>17 really as simple as that.</p> <p>18 BY MR. GISLESON:</p> <p>19 Q. If someone wants to know what strategy a</p> <p>20 particular TPP followed in response to the recall of VCDs,</p> <p>21 it's necessary to ask that TPP?</p> <p>22 MR. HANSEL: Object to the form. Again, this is</p> <p>23 outside the scope of her report.</p> <p>24 BY MR. GISLESON:</p> <p>25 Q. You can answer.</p>	<p style="text-align: right;">Page 176</p> <p>1 Federal Regulations, correct?</p> <p>2 MR. HANSEL: Object to the form.</p> <p>3 A. The FDA, yes, does have a definition for</p> <p>4 bioequivalence.</p> <p>5 BY MR. GEOPPINGER:</p> <p>6 Q. And the FDA's definition is found in the code of</p> <p>7 federal regulations, correct?</p> <p>8 A. Could you be more specific when you say federal</p> <p>9 regulations?</p> <p>10 Q. The Code of Federal Regulations 21CFR of the FDA</p> <p>11 promulgates its regulations.</p> <p>12 A. I did not review.</p> <p>13 Q. Are you aware that the definition of</p> <p>14 bioequivalence is contained -- the FDA's definition is</p> <p>15 contained within the Code of Federal Regulations?</p> <p>16 A. That was not within the scope of my report and I</p> <p>17 did not review that document, but it's my understanding</p> <p>18 though that it should be there but I did not review it. I</p> <p>19 cannot speculate.</p> <p>20 Q. You did not review that definition prior to</p> <p>21 preparing your report, correct?</p> <p>22 A. No. I reviewed the definition. I did not -- if</p> <p>23 you're referring to a particular document that's not</p> <p>24 consistent in my report, that's what I'm referring to.</p> <p>25 Q. I'm sorry, I don't understand the answer.</p>
<p style="text-align: right;">Page 175</p> <p>1 A. I don't know that that would be public</p> <p>2 information, but if you were a member or a -- engaged with</p> <p>3 a TPP, I would -- that information would be available to</p> <p>4 you.</p> <p>5 Q. Are you aware of any public documents that</p> <p>6 identify the different strategies that TPPs took in</p> <p>7 response to the VCD recall?</p> <p>8 A. Public information?</p> <p>9 Q. Yes.</p> <p>10 A. No. The FDA offered guidance on the recall.</p> <p>11 That was public information.</p> <p>12 MR. GISLESON: Those are the questions I have.</p> <p>13 Thank you very much for your time.</p> <p>14 THE WITNESS: You're welcome.</p> <p>15 MR. KERNER: Any other Defendants on the Zoom?</p> <p>16 MR. GEOPPINGER: Yes. Yes. I just have a couple</p> <p>17 brief follow-up questions. I just want to clarify</p> <p>18 something for the record.</p> <p>19 REDIRECT EXAMINATION</p> <p>20 BY MR. GEOPPINGER:</p> <p>21 Q. Good afternoon, Doctor. I know it's getting</p> <p>22 late, so I'll be brief. My name's Jeff Geoppinger. I</p> <p>23 represent AmeriSourceBergen.</p> <p>24 Doctor, you would agree with me that the</p> <p>25 definition of bioequivalent can be found in the Code of</p>	<p style="text-align: right;">Page 177</p> <p>1 MR. HANSEL: Do you have a document you can show</p> <p>2 the witness to ask her if she reviewed it?</p> <p>3 MR. GEOPPINGER: No.</p> <p>4 BY MR. GEOPPINGER:</p> <p>5 Q. My question is, Doctor, in a -- in the -- in the</p> <p>6 process of preparing your report, did you review the</p> <p>7 definition of bioequivalent contained within the Code of</p> <p>8 Federal Regulations?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. On -- in -- a moment ago you referenced</p> <p>11 Paragraph 33 of your report when asked about that</p> <p>12 definition.</p> <p>13 A. Uh-huh.</p> <p>14 Q. Would you agree with me, Doctor, that the</p> <p>15 language in Paragraph 33 of your report is not the</p> <p>16 definition of bioequivalence from the Code of Federal</p> <p>17 Regulations?</p> <p>18 A. No, I don't agree with you.</p> <p>19 Q. Is it your testimony that the language in</p> <p>20 Paragraph 33 of your report is the definition of</p> <p>21 bioequivalence from the Code of Federal Regulations?</p> <p>22 A. To my knowledge.</p> <p>23 Q. Okay. When using the term bioequivalence in your</p> <p>24 report, did you intend to use it as it is defined by the</p> <p>25 FDA in the Code of Federal Regulations?</p>


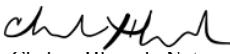
<p style="text-align: right;">Page 178</p> <p>1 MR. HANSEL: Object to the form. Calls for a</p> <p>2 legal conclusion. Beyond the scope.</p> <p>3 A. I believe my definition in my report captures</p> <p>4 what a bioequivalent drug product -- captures the</p> <p>5 definition appropriately.</p> <p>6 BY MR. GEOPPINGER:</p> <p>7 Q. I will agree that Paragraph 33 of your report</p> <p>8 cites a therapeutic equivalence code from the Orange Book</p> <p>9 for bioequivalent drug products. My question is about the</p> <p>10 term bioequivalence as used in the CFR.</p> <p>11 When you used the term bioequivalence in your</p> <p>12 report, are you using it as defined in the Code of Federal</p> <p>13 Regulations?</p> <p>14 MR. HANSEL: I -- I object. It has -- there's no</p> <p>15 foundation.</p> <p>16 A. Since I'm unclear of your question, I prefer not</p> <p>17 to answer.</p> <p>18 BY MR. GEOPPINGER:</p> <p>19 Q. I'll try to answer -- ask it again and make it</p> <p>20 more clear. When you used the word bioequivalence in your</p> <p>21 report, did you -- are you using it as it is defined by the</p> <p>22 Code of Federal Regulations?</p> <p>23 MR. HANSEL: I -- I object. Mr. Geoppinger, are</p> <p>24 you asking the witness to assume that the word</p> <p>25 bioequivalent is only defined one time in the entire</p>	<p style="text-align: right;">Page 180</p> <p>1 question is pending.</p> <p>2 MR. MESTRE: I just want to know the time, so we</p> <p>3 don't go over.</p> <p>4 MR. GEOPPINGER: I'm sorry. I'm in the middle of</p> <p>5 my questions. Why do we need a time check?</p> <p>6 MR. HANSEL: Well, not if the time's almost up.</p> <p>7 MR. MESTRE: I just don't know.</p> <p>8 MR. KERNER: Until she answers the questions</p> <p>9 rather than interrupting him in the middle of his</p> <p>10 examination.</p> <p>11 MR. GEOPPINGER: Excuse me. I have a question</p> <p>12 pending. Is we -- are we still on the record?</p> <p>13 MS. ISIDRO: We are.</p> <p>14 MR. KERNER: Yes, we are.</p> <p>15 MR. GEOPPINGER: Okay. Thank you.</p> <p>16 BY MR. GEOPPINGER:</p> <p>17 Q. Doctor, my -- my question -- I just want to</p> <p>18 clarify because I think we're missing each other here.</p> <p>19 My question is about the term bioequivalence, not</p> <p>20 the term bioequivalent drug products.</p> <p>21 MR. HANSEL: Excuse me, did you say bioequivalent</p> <p>22 with a T or bioequivalence with a C-E?</p> <p>23 MR. GEOPPINGER: I'm talking about the word used</p> <p>24 on -- in Paragraph 59, the last word of that</p> <p>25 paragraph: B-I-O-E-Q-U-I-V-A-L-E-N-C-E,</p>
<p style="text-align: right;">Page 179</p> <p>1 Code of Federal Regulations?</p> <p>2 MR. GEOPPINGER: I'm not asking her to assume. I</p> <p>3 think she already testified that she's aware that the</p> <p>4 word is defined in the -- by the FDA in the Code of</p> <p>5 Federal Regulations.</p> <p>6 A. I believe my definition captures what a bio- --</p> <p>7 is accurate as to what a bioequivalent drug product is.</p> <p>8 If you're asking if I've memorized the Federal</p> <p>9 Regulation's definition for bioequivalence word for word,</p> <p>10 that was -- that's -- I don't have that memorized word for</p> <p>11 word but I'm confident that my definition here captures the</p> <p>12 appropriate definition for bioequivalent drug product.</p> <p>13 BY MR. GEOPPINGER:</p> <p>14 Q. I'm not asking, Doctor, I'm not asking you if</p> <p>15 you've memorized it and I'm not asking about the -- the</p> <p>16 term bioequivalent drug products. That's not what I'm</p> <p>17 asking about.</p> <p>18 I'm asking about the word bioequivalence.</p> <p>19 MR. MESTRE: Can we get an update on the time,</p> <p>20 please?</p> <p>21 BY MR. GEOPPINGER:</p> <p>22 Q. Doctor, when you use the --</p> <p>23 MR. HANSEL: Just a minute, Mr. Geoppinger.</p> <p>24 We're just doing a time check here.</p> <p>25 MR. KERNER: You're also doing it while the</p>	<p style="text-align: right;">Page 181</p> <p>1 bioequivalence.</p> <p>2 BY MR. GEOPPINGER:</p> <p>3 Q. When you use that word, Doctor, in Paragraph 59,</p> <p>4 are you using it in the sense that it is defined in the --</p> <p>5 in the Code of Federal Regulations?</p> <p>6 MR. HANSEL: Object to the form. Foundation.</p> <p>7 You have not told her how it's defined in the Code of</p> <p>8 Federal Regulations. You have not shown her the</p> <p>9 purported definition in the vast Code of Federal</p> <p>10 Regulations to which you are alluding.</p> <p>11 I object to the form of the question.</p> <p>12 MR. GEOPPINGER: Counsel, I -- she's already</p> <p>13 testified she -- she's aware of the definition in the</p> <p>14 Code of Federal Regulations. Additionally --</p> <p>15 MR. HANSEL: Well, you have represented that the</p> <p>16 definition that she used from the FDA Orange Book of</p> <p>17 bioequivalent drug products is not in the Code of</p> <p>18 Federal Regulations. There's no foundation here.</p> <p>19 But please go ahead and answer, if you can.</p> <p>20 THE WITNESS: Okay.</p> <p>21 MR. KERNER: Now that you're done coaching the</p> <p>22 witness.</p> <p>23 MR. GEOPPINGER: Yeah. Counsel, there's a</p> <p>24 deposition protocol, Counsel, and the Plaintiffs in</p> <p>25 this case have taken great issue with speaking</p>

<p style="text-align: right;">Page 182</p> <p>1 objections. So I caution you that you should probably</p> <p>2 review that protocol and understand what the scope of</p> <p>3 your objections can be because that was way outside of</p> <p>4 the protocol here.</p> <p>5 MR. HANSEL: I'm glad you brought that up. Part</p> <p>6 of the --</p> <p>7 MR. KERNER: Why don't we let her answer this</p> <p>8 question?</p> <p>9 MR. HANSEL: Part of the guidelines in this court</p> <p>10 are that follow-up questions such as yours,</p> <p>11 Mr. Geoppinger, are limited to questions not covered</p> <p>12 earlier or questions specific to a Defendant.</p> <p>13 Attorney Isidro covered bioequivalence extensively in</p> <p>14 her -- her examination and so I don't believe your</p> <p>15 questioning is within the permitted scope.</p> <p>16 So please, please wrap it up.</p> <p>17 BY MR. GEOPPINGER:</p> <p>18 Q. Doctor, I'll ask the question hopefully for the</p> <p>19 last time.</p> <p>20 A. Okay.</p> <p>21 Q. When you use the word bioequivalence as it is</p> <p>22 written in -- as the last word of Paragraph 59 of your</p> <p>23 report, are you using that word as it is defined in the</p> <p>24 Code of Federal Regulations?</p> <p>25 A. I am using that word in the context of sameness,</p>	<p style="text-align: right;">Page 184</p> <p>1 MR. HANSEL: Object to the form.</p> <p>2 A. As it pertains to Number 59 which you</p> <p>3 specifically asked me about, I have answered your question.</p> <p>4 MR. GEOPPINGER: Thank you, Doctor. I don't have</p> <p>5 any more questions.</p> <p>6 MR. KERNER: Any other Defendants on the -- the</p> <p>7 Zoom have questions?</p> <p>8 MR. HANSEL: Hearing none, it's -- do the</p> <p>9 Defendants have any further questions?</p> <p>10 MS. ISIDRO: I have just a couple more questions.</p> <p>11 RE CROSS-EXAMINATION</p> <p>12 BY MS. ISIDRO:</p> <p>13 Q. Without identifying any names, are any of the</p> <p>14 TPPs who are involved in this litigation current clients of</p> <p>15 yours?</p> <p>16 A. No.</p> <p>17 Q. Without identifying any names, are any of the</p> <p>18 TPPs involved in this litigation former clients of yours?</p> <p>19 A. No.</p> <p>20 Q. And have you ever worked for any of the entities</p> <p>21 who are Defendants in this litigation?</p> <p>22 A. No.</p> <p>23 MS. ISIDRO: Any questions?</p> <p>24 MR. HANSEL: Yes. Yes, I do. Are you finished?</p> <p>25 MS. ISIDRO: For the moment, yes. I may have</p>
<p style="text-align: right;">Page 183</p> <p>1 that the generic drug was the same as the reference listed</p> <p>2 drug product for safety and effectiveness.</p> <p>3 MR. MESTRE: So hold on. This should not be</p> <p>4 controversial now. There's no pending question. It's</p> <p>5 5:30 in the afternoon. I'd like to know the amount of</p> <p>6 time that's left.</p> <p>7 THE COURT REPORTER: Five hours seven minutes.</p> <p>8 MR. MESTRE: Thank you.</p> <p>9 BY MR. GEOPPINGER:</p> <p>10 Q. Doctor, that's your definition of bioequivalence?</p> <p>11 A. You asked me how I used it in the context of the</p> <p>12 sentence in Number 59 where it says the presence of the</p> <p>13 contaminant rendered the Manufacturer Defendants' versions</p> <p>14 of VCDs not equivalent to the branded product as indicated</p> <p>15 in the Orange Book which serves as the source of truth for</p> <p>16 bioequivalence and permits substitutability of the generic</p> <p>17 drug when it meets those -- that criteria.</p> <p>18 The drug did -- that we're -- so it did not meet</p> <p>19 the criteria by presence of the contaminants, was not the</p> <p>20 same as the branded drug, would not have met FDA approval</p> <p>21 for bioequivalence, and not the same as the referenced</p> <p>22 listed product, would not have been listed in the Orange</p> <p>23 Book.</p> <p>24 Q. Doctor, have you now told me how you've defined</p> <p>25 bioequivalence in your report?</p>	<p style="text-align: right;">Page 185</p> <p>1 some follow-up after you.</p> <p>2 MR. HANSEL: Okay. Thank you.</p> <p>3 FURTHER DIRECT EXAMINATION</p> <p>4 BY MR. HANSEL:</p> <p>5 Q. Dr. Panagos, thank you for your patience on a</p> <p>6 long day. I have a few questions for you on behalf of the</p> <p>7 Plaintiffs.</p> <p>8 You may recall that Mr. Gisleson asked you some</p> <p>9 questions regarding whether you were aware of any</p> <p>10 third-party payors in particular who -- who paid for</p> <p>11 contaminated Valsartan and who were seeking a refund.</p> <p>12 Before he asked you about that after the lawsuit was filed,</p> <p>13 he asked you about it in general.</p> <p>14 Are you aware that Plaintiffs Maine Automobile</p> <p>15 Dealers Association Insurance Trust and MSP Recovery Series</p> <p>16 allege in the complaint that they or their assignors in the</p> <p>17 case of MSP paid for contaminated Valsartan?</p> <p>18 MS. ISIDRO: Objection.</p> <p>19 A. Yes. That's within the complaint.</p> <p>20 BY MR. HANSEL:</p> <p>21 Q. And in your report in Appendix A you list various</p> <p>22 materials you reviewed for your report, right?</p> <p>23 A. Yes.</p> <p>24 Q. And among those materials are four categories of</p> <p>25 materials that contain data showing payments by MADA and</p>

<p style="text-align: right;">Page 186</p> <p>1 MSP and those are the MADA Third Party Payor Plaintiff's</p> <p>2 Fact Sheet, the MSP Third Party Payor Plaintiff's Facts</p> <p>3 Sheet --</p> <p>4 MS. ISIDRO: Objection.</p> <p>5 BY MR. HANSEL:</p> <p>6 Q. -- the --</p> <p>7 MR. KERNER: Objection. Leading.</p> <p>8 MR. HANSEL: I'm not finished.</p> <p>9 BY MR. HANSEL:</p> <p>10 Q. -- the MADA claims data for recalled Valsartan,</p> <p>11 and excerpts from MSP data July 6th, 2021.</p> <p>12 Did you -- did you review that data?</p> <p>13 MS. ISIDRO: Objection.</p> <p>14 A. Yes.</p> <p>15 BY MR. HANSEL:</p> <p>16 Q. Is that the type of data that you ordinarily</p> <p>17 review in the course of your professional career?</p> <p>18 A. Yes, it is.</p> <p>19 MR. KERNER: Hang on a second. There seems to be</p> <p>20 a bit of echo in the room now. If somebody who is on</p> <p>21 the Zoom could mute themselves, that would be helpful.</p> <p>22 BY MR. HANSEL:</p> <p>23 Q. Did that data show in the case of MADA that --</p> <p>24 that it paid for contaminated lots of Valsartan that were</p> <p>25 subject to the contamination alleged in the complaint?</p>	<p style="text-align: right;">Page 188</p> <p>1 A. Yes.</p> <p>2 BY MR. HANSEL:</p> <p>3 Q. Do you understand that the proposed third-party</p> <p>4 payor class consists of third-party payors as defined in</p> <p>5 Paragraph 14 of your report?</p> <p>6 A. Yes.</p> <p>7 Q. Specifically all third-party payors in the United</p> <p>8 States and its territories and possessions that, since at</p> <p>9 least January 1, 2012, to the present, paid any amount of</p> <p>10 money for Valsartan-containing drug, intended for personal</p> <p>11 or household use, that was manufactured, distributed, or</p> <p>12 sold by any Active Pharmaceutical Ingredient, Finished</p> <p>13 Dose, Wholesaler, or Repackager/Relabeler Defendant.</p> <p>14 MS. ISIDRO: Objection.</p> <p>15 BY MR. HANSEL:</p> <p>16 Q. Is that your understanding?</p> <p>17 A. Yes.</p> <p>18 Q. Do you understand that the proposed class so</p> <p>19 defined is in effect, at least in part, suing for a refund,</p> <p>20 the word used by Attorney Gisleson, suing for a refund, at</p> <p>21 least in part in this lawsuit?</p> <p>22 A. Yes.</p> <p>23 Q. Today you've heard a lot of questions and</p> <p>24 objections about whether certain topics were within the</p> <p>25 scope of your report. Do you remember that?</p>
<p style="text-align: right;">Page 187</p> <p>1 ZOOM PARTICIPANT: Objection: Foundation.</p> <p>2 A. The data showed that the claims -- there were</p> <p>3 paid claims.</p> <p>4 BY MR. HANSEL:</p> <p>5 Q. And did the -- did the MSP data show paid claims</p> <p>6 of MSP's assignors?</p> <p>7 A. Yes.</p> <p>8 Q. Do you understand that MSP's assignors are</p> <p>9 third-party payors?</p> <p>10 A. Yes.</p> <p>11 Q. Do you understand that MSP is an -- is an</p> <p>12 assignee of third-party payors for Valsartan?</p> <p>13 A. Yes, I do.</p> <p>14 Q. Do you understand that MSP is suing in its</p> <p>15 capacity as a holder of valid assignments of those -- of</p> <p>16 the claims of its assignors?</p> <p>17 MS. ISIDRO: Objection.</p> <p>18 ZOOM PARTICIPANT: Objection. Legal conclusion</p> <p>19 and leading.</p> <p>20 A. Yes.</p> <p>21 BY MR. HANSEL:</p> <p>22 Q. And do you understand that MSP alleges in the</p> <p>23 complaint that it stands in the shoes in effect of its</p> <p>24 assignor TPPs?</p> <p>25 MS. ISIDRO: Objection.</p>	<p style="text-align: right;">Page 189</p> <p>1 A. Yes.</p> <p>2 Q. Does your report set forth the scope of your</p> <p>3 report accurately?</p> <p>4 A. Yes.</p> <p>5 MS. ISIDRO: Objection.</p> <p>6 MR. HANSEL: Let me take a short break and see if</p> <p>7 I have any more questions.</p> <p>8 MR. KERNER: How long --</p> <p>9 MR. HANSEL: Under five minutes.</p> <p>10 THE VIDEOGRAPHER: The time is 5:33, and we're</p> <p>11 going off record.</p> <p>12 (Break taken.)</p> <p>13 THE VIDEOGRAPHER: The time is 5:38 p.m., and</p> <p>14 we're back on record.</p> <p>15 MR. HANSEL: No further questions.</p> <p>16 Thank you, Dr. Panagos.</p> <p>17 THE WITNESS: You're welcome.</p> <p>18 MR. KERNER: Anybody else on the phone?</p> <p>19 MR. GISLESON: Yeah. Just a brief follow-up.</p> <p>20 This is John Gisleson again for Aurobindo.</p> <p>21 FURTHER CROSS-EXAMINATION</p> <p>22 BY MR. GISLESON:</p> <p>23 Q. You were asked about the MADA, M-A-D-A, claims</p> <p>24 data. Do you have any understanding as to how MADA managed</p> <p>25 its beneficiaries' prescriptions following the VCD recall?</p>

<p style="text-align: right;">Page 190</p> <p>1 A. The claims data demonstrates -- shows claims that</p> <p>2 were paid for.</p> <p>3 Q. Do you know what strategy MADA followed in</p> <p>4 response to the VCD recall?</p> <p>5 A. That was not within the scope of my review.</p> <p>6 Q. Did you do any investigation to determine how</p> <p>7 MADA managed its patients, its beneficiaries' prescriptions</p> <p>8 following the VCD recall in connection with your review of</p> <p>9 the claims data?</p> <p>10 A. I reviewed the claims data which showed that the</p> <p>11 claims were paid for. That's it.</p> <p>12 Q. Did you seek to learn how MADA managed the recall</p> <p>13 of VCDs?</p> <p>14 A. That's not within the scope of my -- of the</p> <p>15 opinion I was asked to render.</p> <p>16 Q. So you didn't do it?</p> <p>17 A. I do not wish to comment or speculate on the</p> <p>18 strategy that they took. I reviewed the claims data which</p> <p>19 showed that they paid for claims for those drugs.</p> <p>20 Q. Do you know whether MADA at any point implemented</p> <p>21 a block concerning NDCs or VCDs that contained nitrosamine</p> <p>22 impurities?</p> <p>23 A. I do not know.</p> <p>24 Q. Pardon me?</p> <p>25 A. I do not know.</p>	<p style="text-align: right;">Page 192</p> <p>1 paid for.</p> <p>2 Q. Did you do any investigation to determine whether</p> <p>3 any of MSP's assignors, assignor TPPs, implemented blocks</p> <p>4 at any point concerning VCDs containing nitrosamine</p> <p>5 impurities?</p> <p>6 MR. HANSEL: Asked and answered.</p> <p>7 A. I was not asked to review their strategies. I</p> <p>8 reviewed the claims data.</p> <p>9 BY MR. GISLESON:</p> <p>10 Q. And as a result, you have no knowledge as to what</p> <p>11 those strategies were, correct?</p> <p>12 MR. HANSEL: Objection.</p> <p>13 A. That was not --</p> <p>14 MR. HANSEL: Asked and answered. Object to the</p> <p>15 form. Repetitive.</p> <p>16 MR. GISLESON: I'm just looking for a direct</p> <p>17 answer to a clear question.</p> <p>18 MR. HANSEL: Your question assumes that whatever</p> <p>19 payment data she already told you she reviewed can be</p> <p>20 completely divorced from whatever their strategy is,</p> <p>21 since you brought it up.</p> <p>22 BY MR. GISLESON:</p> <p>23 Q. You can answer the question.</p> <p>24 A. If and when they had a strategy, I was not a</p> <p>25 participant or have knowledge of what that was. I have</p>
<p style="text-align: right;">Page 191</p> <p>1 Q. And as to MSP's assignors, do you know whether --</p> <p>2 strike that.</p> <p>3 Did you do any investigation to determine how any</p> <p>4 of MSP's assignors managed the VCD recall -- recalls</p> <p>5 following the identification of nitrosamine impurities?</p> <p>6 A. That was not within the scope of my report. I</p> <p>7 reviewed the claims data that -- that showed that they paid</p> <p>8 for the claims.</p> <p>9 Q. So as a result of the work that you did in this</p> <p>10 case, you have no understanding as to how MSP's assignors</p> <p>11 managed the VCD recall following the discovery of</p> <p>12 nitrosamine impurities, correct?</p> <p>13 MR. HANSEL: Object to the form. Outside the</p> <p>14 scope. Asked and answered.</p> <p>15 MR. GISLESON: It hasn't been answered.</p> <p>16 BY MR. GISLESON:</p> <p>17 Q. You can answer the question, please.</p> <p>18 MR. HANSEL: Same objection.</p> <p>19 A. They were assigned claims data. I did not review</p> <p>20 any further assignments or agreements.</p> <p>21 BY MR. GISLESON:</p> <p>22 Q. Including any strategies that any of those</p> <p>23 assignors followed to manage the recalls, correct?</p> <p>24 A. That was not in the scope of my review. I</p> <p>25 reviewed the claims data that shows that those claims were</p>	<p style="text-align: right;">Page 193</p> <p>1 reviewed the claims data that shows that the claims were</p> <p>2 paid for.</p> <p>3 Q. Any other information than claims data?</p> <p>4 MR. HANSEL: Objection. Asked and answered.</p> <p>5 A. Could you be more specific?</p> <p>6 BY MR. GISLESON:</p> <p>7 Q. Sure. What was the information in the claims</p> <p>8 data that was important to you?</p> <p>9 A. Claims data demonstrated that the plan paid a</p> <p>10 portion of the medication and the member paid a portion.</p> <p>11 Q. Anything else?</p> <p>12 A. Indicating that that was re- -- medication was</p> <p>13 reimbursed or plan paid for.</p> <p>14 Q. Anything else?</p> <p>15 MR. HANSEL: Object to the form.</p> <p>16 A. I -- the claims data followed a standard claims</p> <p>17 data format, typical of what we see in the industry when</p> <p>18 you're reviewing claims.</p> <p>19 BY MR. GISLESON:</p> <p>20 Q. Did the claims data identify specific</p> <p>21 individual -- the names of specific individuals?</p> <p>22 A. If you're asking in general if claims data can</p> <p>23 include those fields, those fields -- can you be more</p> <p>24 specific as to how you're asking the question and with</p> <p>25 which --</p>

<p style="text-align: right;">Page 194</p> <p>1 Q. Sure. Did the claims data that you reviewed</p> <p>2 identify the names of the patients who consumed the VCDs?</p> <p>3 A. Not that I recall, no.</p> <p>4 Q. I'm sorry, no?</p> <p>5 MR. HANSEL: Would you like the court reporter to</p> <p>6 read back the answer?</p> <p>7 MR. GISLESON: I couldn't hear.</p> <p>8 MR. HANSEL: Would the court reporter please read</p> <p>9 back the answer?</p> <p>10 (The requested portion was read back.)</p> <p>11 MR. GISLESON: Thank you very much.</p> <p>12 Those are all the questions I have. Thank you</p> <p>13 for your time and your patience.</p> <p>14 THE WITNESS: All right. Thank you.</p> <p>15 MR. DORNER: I have questions within the scope of</p> <p>16 that.</p> <p>17 FURTHER FURTHER DIRECT EXAMINATION</p> <p>18 BY MR. DORNER:</p> <p>19 Q. Doctor, my name is Drew Dorner. I'm here on</p> <p>20 behalf of CHP.</p> <p>21 The claims data that you just referred to would</p> <p>22 only reflect costs associated with the transaction at the</p> <p>23 time of the adjudication of the claim; is that right?</p> <p>24 MR. HANSEL: Object to the form. Lack of</p> <p>25 foundation.</p>	<p style="text-align: right;">Page 196</p> <p>1 records. Am I understanding that correctly?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Where the claims data reflect that</p> <p>4 particular claim, any amount of money associated with that</p> <p>5 transaction is -- it reflects only money exchanged at the</p> <p>6 time of that transaction, right?</p> <p>7 A. It reflects the plan paid and any member paid</p> <p>8 amounts at the date of service.</p> <p>9 Q. Okay. I understand. And so if either prior to</p> <p>10 or subsequent to the date of service some amount of money</p> <p>11 was also exchanged that is related to the -- indirectly or</p> <p>12 directly related to the claim, that would not be reflected</p> <p>13 in the particular set of claims data that you were</p> <p>14 referring to when you were talking with Mr. Gisleson; is</p> <p>15 that right?</p> <p>16 MR. HANSEL: I object to the form of the</p> <p>17 question. Lack of foundation.</p> <p>18 BY MR. DORNER:</p> <p>19 Q. You can answer.</p> <p>20 A. Could you be more specific when you say exchange</p> <p>21 of money before or following outside of a claims data?</p> <p>22 Q. Sure. And let me give an example. In -- in some</p> <p>23 cases a PBM or a TPP might benefit from a rebate, for</p> <p>24 example, from a drug manufacturer; is that right?</p> <p>25 MR. HANSEL: Objection. Objection. This is</p>
<p style="text-align: right;">Page 195</p> <p>1 Mr. Dorner, do you have an exhibit?</p> <p>2 MR. DORNER: The witness has seen the exhibits,</p> <p>3 the claims data that she's referring to that she's</p> <p>4 reviewed.</p> <p>5 MR. HANSEL: Well, it's not an exhibit to this</p> <p>6 deposition.</p> <p>7 MR. DORNER: I'm not making it an exhibit. I'd</p> <p>8 like an answer to my question.</p> <p>9 A. I will answer generally that claims data that has</p> <p>10 a plan paid amount or claims data that it's at the point of</p> <p>11 adjudication.</p> <p>12 BY MR. DORNER:</p> <p>13 Q. Okay. And that only reflects some -- some of --</p> <p>14 some amount of money that exchanges at the time of that</p> <p>15 adjudication, but not, for example, any payments that might</p> <p>16 be made to a TPP well before the adjudication or any</p> <p>17 payments that might be made to a TPP after the</p> <p>18 adjudication; is that accurate?</p> <p>19 MR. HANSEL: Object to the form. Lack of</p> <p>20 foundation.</p> <p>21 A. I'm not sure what you're asking.</p> <p>22 BY MR. DORNER:</p> <p>23 Q. Sure. If a member of a TPP makes a claim for a</p> <p>24 medication, it's your testimony that there is claims data</p> <p>25 associated with that that would be reflected in the TPP's</p>	<p style="text-align: right;">Page 197</p> <p>1 beyond the scope of her report.</p> <p>2 MR. DORNER: Hold on. This is -- no. No. We're</p> <p>3 not getting into speaking objections. She asked for a</p> <p>4 specific example. I'm giving her one. All right.</p> <p>5 You can object to the form.</p> <p>6 THE WITNESS: Okay.</p> <p>7 MR. HANSEL: I object to the form. It's beyond</p> <p>8 the scope of her report. It has nothing to do with</p> <p>9 her report. Other experts are addressing this issue.</p> <p>10 BY MR. DORNER:</p> <p>11 Q. You can answer the question, ma'am.</p> <p>12 A. The claims data reflects what the plan paid.</p> <p>13 Q. On the date of service, right?</p> <p>14 A. On the date of service.</p> <p>15 Q. It would not reflect in the example that I gave</p> <p>16 something like a refund; is that right?</p> <p>17 MR. HANSEL: Object to the form.</p> <p>18 A. Are you referring -- your question is unclear.</p> <p>19 Are you referring to refund? You said rebate. I think</p> <p>20 you're --</p> <p>21 BY MR. DORNER:</p> <p>22 Q. Yeah. I -- I -- I caught the same error. So the</p> <p>23 example I gave was a rebate. I apologize. It wouldn't</p> <p>24 reflect a -- a rebate subsequent to the date of</p> <p>25 adjudication; is that right?</p>

<p style="text-align: right;">Page 198</p> <p>1 MR. HANSEL: Objection: Beyond the scope.</p> <p>2 A. I've answered that the claims data represents</p> <p>3 what the plan paid at the date of service. That amount is</p> <p>4 found clearly within the claims data.</p> <p>5 BY MR. DORNER:</p> <p>6 Q. Well, I appreciate your answer, but I would like</p> <p>7 an answer to my question. My question was: The -- a</p> <p>8 subsequent rebate would not be reflected in the type of</p> <p>9 claims data that you were referring to in your prior</p> <p>10 testimony to Mr. Gisleson; is that accurate?</p> <p>11 MR. HANSEL: Object to the form. Calls for</p> <p>12 speculation, beyond the scope, asked and answered, no</p> <p>13 foundation.</p> <p>14 BY MR. DORNER:</p> <p>15 Q. You can answer.</p> <p>16 A. To the best of my knowledge, if a rebate applied</p> <p>17 to these type of drugs, it would not be within the claims</p> <p>18 data.</p> <p>19 Q. And if there were similar payments, not</p> <p>20 necessarily rebates but things like governmental subsidies</p> <p>21 that might also be paid well after the date of</p> <p>22 adjudication, that also wouldn't be reflected in the claims</p> <p>23 data you were referring to; is that accurate?</p> <p>24 MR. HANSEL: Object to the form. Lack of</p> <p>25 foundation, calls for speculation, beyond the scope of</p>	<p style="text-align: right;">Page 200</p> <p>1 CERTIFICATE OF OATH</p> <p>2</p> <p>3 STATE OF FLORIDA</p> <p>4 COUNTY OF MIAMI-DADE</p> <p>5</p> <p>6 I, CHELSEA HLAVACH, shorthand reporter and Notary</p> <p>7 Public, State of Florida, certify that KALI PANAGOS,</p> <p>8 PHARM.D., R.PH, appeared before me and was duly</p> <p>9 sworn/affirmed Witness my hand and official seal this 21st</p> <p>10 day of January, 2022.</p> <p>11</p> <p>12 Witness my hand and official seal this 1st day of</p> <p>13 February, 2022.</p> <p>14</p> <p>15</p> <p>16</p> <p>17  Chelsea Hlavach, Notary Public State of Florida, My Commission: GG352672, Expires: August 11, 2023</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 199</p> <p>1 the report, asked and answered.</p> <p>2 You need to wrap this up, Mr. Dorner. It has</p> <p>3 nothing to do with Dr. Panagos's report.</p> <p>4 BY MR. DORNER:</p> <p>5 Q. You can answer.</p> <p>6 A. I don't know.</p> <p>7 MR. DORNER: Okay. I have no further questions.</p> <p>8 MR. KERNER: Anybody else on the Zoom?</p> <p>9 MR. HANSEL: Anyone else in the room?</p> <p>10 MS. ISIDRO: Nothing from me, no.</p> <p>11 MR. HANSEL: We will read and sign.</p> <p>12 Thank you very much, Dr. Panagos, and Chelsea,</p> <p>13 videographer, thanks very much, and for your</p> <p>14 hospitality, Jorge, thank you.</p> <p>15 THE VIDEOGRAPHER: That concludes today's</p> <p>16 deposition. The time is 5:52 p.m., and we're going</p> <p>17 off record.</p> <p>18 (The deposition concluded at 5:52 p.m.)</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 201</p> <p>1 CERTIFICATE OF REPORTER</p> <p>2</p> <p>3 STATE OF FLORIDA</p> <p>4 COUNTY OF MIAMI-DADE</p> <p>5</p> <p>6 I, CHELSEA HLAVACH, Shorthand Reporter and Notary</p> <p>7 Public, State of Florida, HEREBY CERTIFY that I was</p> <p>8 authorized to and did stenographically report the</p> <p>9 deposition of KALI PANAGOS, PHARM.D., R.PH; that a review</p> <p>10 of the transcript was requested; and the foregoing</p> <p>11 transcript, pages 10 through 199, inclusive, is a true and</p> <p>12 accurate record of my stenographic notes.</p> <p>13 I FURTHER CERTIFY that I am not a relative,</p> <p>14 employee, attorney, or counsel to any of the parties, nor</p> <p>15 am I a relative or employee of any of the parties' attorney</p> <p>16 or counsel connected with the action, nor am I financially</p> <p>17 interested in the action.</p> <p>18 Dated this 21st day of January, 2022.</p> <p>19</p> <p>20</p> <p>21</p> <p>22  Chelsea Hlavach, Notary Public, State of Florida at Large</p> <p>23</p> <p>24</p> <p>25</p>

<p style="text-align: right;">Page 202</p> <p>1 GREGORY HANSEL, ESQUIRE 2 ghansel@preti.com 3 February 4, 2022 4 RE: In Re: Valsartan, Losartan, Et Al 5 1/21/2022, Kali Panagos, Pharm.D (#5024986) 6 The above-referenced transcript is available for 7 review. 8 Within the applicable timeframe, the witness should 9 read the testimony to verify its accuracy. If there are 10 any changes, the witness should note those with the 11 reason, on the attached Errata Sheet. 12 The witness should sign the Acknowledgment of 13 Deponent and Errata and return to the deposing attorney. 14 Copies should be sent to all counsel, and to Veritext at 15 erratas-cs@veritext.com 16 17 Return completed errata within 30 days from 18 receipt of testimony. 19 If the witness fails to do so within the time 20 allotted, the transcript may be used as if signed. 21 22 Yours, 23 Veritext Legal Solutions 24 25</p>	<p style="text-align: right;">Page 204</p> <p>1 In Re: Valsartan, Losartan, Et Al 2 Kali Panagos, Pharm.D (#5024986) 3 ACKNOWLEDGEMENT OF DEPONENT 4 I, Kali Panagos, Pharm.D, do hereby declare that I 5 have read the foregoing transcript, I have made any 6 corrections, additions, or changes I deemed necessary as 7 noted above to be appended hereto, and that the same is 8 a true, correct and complete transcript of the testimony 9 given by me. 10 11 _____ 12 Kali Panagos, Pharm.D Date 13 *If notary is required 14 SUBSCRIBED AND SWORN TO BEFORE ME THIS 15 _____ DAY OF _____, 20____. 16 17 18 _____ 19 NOTARY PUBLIC 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 203</p> <p>1 In Re: Valsartan, Losartan, Et Al 2 Kali Panagos, Pharm.D (#5024986) 3 E R R A T A S H E E T 4 PAGE____ LINE____ CHANGE_____ 5 _____ 6 REASON_____ 7 PAGE____ LINE____ CHANGE_____ 8 _____ 9 REASON_____ 10 PAGE____ LINE____ CHANGE_____ 11 _____ 12 REASON_____ 13 PAGE____ LINE____ CHANGE_____ 14 _____ 15 REASON_____ 16 PAGE____ LINE____ CHANGE_____ 17 _____ 18 REASON_____ 19 PAGE____ LINE____ CHANGE_____ 20 _____ 21 REASON_____ 22 _____ 23 _____ 24 Kali Panagos, Pharm.D Date 25</p>	

[& - 4]

Page 1

&	15th 3:10	2009 19:15,17,22	270 3:2
& 2:14 3:5 4:10,14 4:19 5:5,9,17,21 7:5	16 8:13	20:14 28:24	27th 4:19
0	16990 3:15	201 8:9	28 100:8,12,18,22 104:8 105:7
02109 4:19	17 8:15	2010 28:24	28202 3:6
04101 2:15	175 8:5	2012 188:9	2875 1:4
07102 3:10	17th 3:20	2015 27:6	29 101:9,11,16 106:22 108:11,15 109:5
07932 4:24	18 97:9,12,18 99:2	2016 65:1	3
08540 6:15	18,750 89:18	2018 28:7,19 35:12 36:5 47:14 93:14 138:18 142:7,11 142:15,19 146:22 150:24	3 8:16 64:16 69:3 70:12 85:13,21 93:4 125:21
1	184 8:5	2019 26:7 37:6,14 45:1 46:25 47:2 47:14	30 3:20 69:3 70:12 202:17
1 8:13 10:5 16:10 16:15 40:14 79:16 98:1 188:9	185 8:6	202 8:9	300 3:17
1/21/2022 202:5	189 8:6	2020 46:9	30305 6:11
10 201:10	19 99:15,18,24 100:19	2021 37:14,17 97:23 186:11	312 5:2
100 3:10,18	190 6:6	2022 1:11 10:4 200:10,13 201:17 202:3	316 6:2
1000 1:14 2:11,22 4:2 10:8	19087 3:2	2023 200:18	32 101:9,11,16 106:23 108:11,16 109:5
1001 5:21 7:5	19103-4196 3:20	203 8:10	32502 6:3
10017 2:4,8	194 8:7	21 1:11 6:15 90:8 100:7,12,18	32nd 5:6
105 13:22	199 201:10	21cfr 176:10	33 109:7,12 171:25 177:11,15,20 178:7
10:49 59:17	1997 18:2	21st 10:4 200:9 201:17	33134 1:15 2:11,23
11 5:10 200:18	1:56 92:25	2200 4:6 6:19	3333 6:11
11:08 59:20	1st 200:12	2220 5:13	3475 3:6
11:24 68:21	2	22695 200:16 201:22	3600 4:6 6:19
12 93:10,14 125:21 141:21 155:8 169:15	2 8:15 17:22,24 40:15 63:17 79:18 80:14,17 93:9 102:19,25 107:5 155:7	227 3:5	375 88:21 89:17
125 8:19	20 38:18 82:24 99:15,18,24 100:19 136:1 204:15	230 5:13	38th 4:10,15
12:17 74:17	200 6:10 8:8	25 103:12	3:09 128:18
12:53 92:22	2000 18:14,22 20:13 27:6	2500 6:11	3:21 128:21
13 8:4	20004 5:22 7:6	2525 1:14 2:11,22 10:7	4
14 97:8,12,18 99:2 100:22 188:5	20004-2166 4:2	260 7:2	4 8:18 90:23,24 103:13 141:20 155:5,7 202:3
1400 5:2	2002 19:12		
15219 4:11,15	2005 20:13		
15219-6401 5:6	2006 19:2		
154 8:4	2008 28:7,19		

[4,500 - adjudicated]

Page 2

4,500 87:20 400 4:23 6:2 88:22 41 109:7,12 42 110:3,7 112:14 112:19,22 113:2 43 110:3,7 113:5 44 113:7 114:20 115:1 44023-4536 3:16 444 3:6 45 115:16 45202-4029 5:2 46 116:18,23 117:25 118:4,11 118:23 119:4,7,12 119:18 172:25 46204-3535 5:10 47 121:11,17 123:10,17,22 124:3,10,13,20 128:13 136:8 143:3 145:11 4:10 153:24 4:34 154:2	56 136:5,6,13 57 136:24 59 140:9,14,22 141:22 180:24 181:3 182:22 183:12 184:2 5:30 183:5 5:33 189:10 5:38 189:13 5:52 1:12 199:16 199:18	9 9 127:20 90 8:18 910 127:11 911 127:20 97 18:25 9:32 1:12 10:4 9th 4:2	accuracy 202:9 accurate 15:21 147:24 179:7 195:18 198:10,23 201:11 accurately 189:3 acknowledgement 204:3 acknowledgment 202:12 actavis 3:13,13 action 201:15,16 actions 1:6 173:3 active 36:24 188:12 activities 169:20 actual 151:8,18 add 12:11 70:15 73:4,12 added 97:23 addition 69:13 71:13 107:19,24 135:11 additional 98:12 100:17 104:18 additionally 181:14 additions 204:6 address 13:21,22 37:1,4 addressing 52:9 197:9 adequate 162:15 adhere 23:2,16 130:25 145:21 146:8 adhered 153:2,2 153:22 adherence 22:5,6 adjudicated 162:18,19
5	6 6 16:20 80:11 97:23 123:17 124:4,10,20 125:4 125:15 142:22 143:7,14 144:4,24 171:25 60 89:13 600 3:5 6:6 60606 5:14 617-213-7001 4:20 617-213-7045 4:20 63105-3443 6:7 66210 7:2 6b 143:2 6d 144:10 6i 145:6,9,16 146:24 147:11 6th 186:11	a a.m. 1:12 10:4 59:17,20 ab 116:17 121:11 ability 15:25 24:20 able 15:21 22:2 23:14 32:14 34:3 64:5 72:25 115:14 abruptly 169:1 170:10 absolutely 88:6 abstracts 80:15 81:6 academia 62:25 academic 51:25 52:22 53:3 54:14 55:24 60:23 82:9 academy 45:16 49:2,6 acceptable 166:17 167:1 168:11,19 acceptance 69:21 74:11 accepted 31:8 34:7 103:17 125:2 127:17 128:2 132:1 153:9 access 171:5,6 accommodate 170:15 account 28:23 30:4 38:15	
5 8:19 97:7 103:13 125:10,11,14 126:5,6,12,20 127:10,19 128:12 50 89:13,16 500 4:23 5024986 202:5 203:2 204:2 505 4:2 52 128:24 130:10 131:10,14,17 53 4:19 55 132:9,15,25 133:8 134:3 135:9 550 3:2	7 701 2:19 5:17 70130 2:19 5:18 704 3:6 75201-7932 4:7 6:20	8 8101 7:2 85 8:16	

[adjudication - answers]

Page 3

adjudication 43:23 162:24 194:23 195:11,15 195:16,18 197:25 198:22 adjunct 20:8 63:20 adjuster 21:18 22:11,15,25 23:5 23:10 adjuster's 23:17 23:18 administer 21:21 40:5 administration 19:16,19 100:6 107:6,15 112:16 113:9,16 114:12 administrative 63:12,22 administrator 40:3,4 administrators 38:22 adopt 102:3 105:15 adults 21:16 adverse 82:3 83:21 advice 37:20 157:25 158:24 advisable 169:1 advise 33:9 41:4 56:24 91:18 168:10 advised 168:14 advisement 20:3 33:21 37:25 advising 30:6 35:18 57:9 170:9	advisors 20:1 35:12 advisory 26:3,9,10 105:1 affiliation 24:1,23 25:2,5,6,14,17,18 affiliations 23:20 26:3 affirm 13:1 affirmed 200:9 affordable 115:19 afternoon 93:3 175:21 183:5 agency 96:5 agency's 150:18 ago 177:10 agree 11:7 91:13 91:21 149:15,21 175:24 177:14,18 178:7 agreed 9:15 103:2 agreement 12:3 agreements 160:16 191:20 ahead 16:9 17:21 85:12 90:22 128:16 153:23 181:19 aid 5:11 21:16 al 202:4 203:1 204:1 albertson 3:8 alfano 4:10,14 allege 185:16 alleged 97:2 186:25 alleges 187:22 allotted 202:20 allow 12:22 30:19 74:6 116:15 171:5	allows 23:13,16 116:13 alluding 181:10 american 44:22 47:10,21 48:21,22 50:1,11 51:3 100:1 amerisourceberg... 175:23 amgen 26:3 amount 34:17 72:14 87:18 89:5 89:21,25 90:2,2,3 183:5 188:9 195:10,14 196:4 196:10 198:3 amounts 87:22 196:8 analysis 32:12 analytics 32:9 anda 67:19 106:5 106:7,15,15 107:2 116:11 117:1 118:15 119:15 121:8,13 123:12 124:5 130:19 131:22 132:4 143:10,17,19,25 144:1 150:14 151:15 173:10 anda's 124:6,24 anesthesia 24:1,9 anesthesiologists 24:15 anesthesiology 24:6 announced 93:15 166:3 announcement 139:23	annoys 69:8 answer 14:11,17 14:18 15:6 33:16 33:23 43:21 66:18 66:24 67:2,25 68:10 69:25 71:11 72:18 77:3 84:5 93:24 94:1,20 106:16 110:21 112:3 115:13,15 117:4 120:16 122:15 126:3 134:14 135:20 137:19 141:15 143:21 156:4,10 156:21 160:14 163:21 166:21 170:21,24 171:20 174:25 176:25 178:17,19 181:19 182:7 191:17 192:17,23 194:6,9 195:8,9 196:19 197:11 198:6,7,15 199:5 answered 15:13 60:8 63:7 66:13 66:15 71:11 72:22 75:15 84:11 94:16 94:17 99:8 111:6 124:14,23 132:22 159:24 163:19 171:17 184:3 191:14,15 192:6 192:14 193:4 198:2,12 199:1 answering 73:2 84:19 answers 72:6,9 180:8
---	--	--	--

[anticoagulation - aspects]

Page 4

anticoagulation 25:11	120:11 126:10 130:14,16 131:22 132:3,4,6 149:17 150:14 151:16	143:19 145:23 149:18,20 151:16 164:23 173:8,8 183:20	articles 52:6,9,12 52:15,18 80:14 81:1 86:19 172:21
anybody 11:25 73:3 189:18 199:8	applications 104:2 131:12 149:24	approvals 57:12 74:22 75:4,12,24 127:3 128:4	asher 3:1
anymore 122:8	applied 144:19 198:16	approved 57:5 60:2,10,18 63:1 66:1 67:7 101:19 101:21,21 105:20 105:24 115:22 116:11 119:21 120:25 123:12,14 124:6,24 127:6 133:11,12,15,16 136:16 147:5,8 151:15 152:22 153:10,10 155:16 171:14 174:15	ashp 8:20 100:1 124:15 127:1
apart 97:2	applies 30:16		aside 78:20
apologize 197:23	apply 52:19 111:12		asked 11:7 26:10 60:7 63:7 66:13 66:19,21,25 67:14 67:21 69:14 71:8 71:12,23 72:7,8,10 72:19 75:14 84:11 92:7,9 94:15 111:5 115:12 124:14,22 141:11 141:12 159:24 163:19 164:11 169:15 171:17 174:11 177:11 183:11 184:3 185:8,12,13 189:23 190:15 191:14 192:6,7,14 193:4 197:3 198:12 199:1
app 88:12	applying 106:15 117:16 130:24	approximate 167:19	asking 12:5 39:19 44:9 57:15,16 68:12,15 87:24 108:23 110:18 118:7 153:15,17 158:22 165:21 169:19 170:16,18 178:24 179:2,8,14 179:14,15,17,18 193:22,24 195:21
appearance 10:17 26:18 27:2	appointment 46:12	approximately 46:24 69:12 89:13 89:15,16,18 167:15	asks 11:14 80:14
appearances 10:14	appreciate 71:1 79:25 198:6	areas 157:21	aspect 29:25 108:15 109:4
appeared 3:3,8,13 3:18,22 4:4,8,13 4:17,21,25 5:4,8 5:11,15,19,23 6:4 6:8,13,17,21 7:3,7 7:10 200:8	appropriate 30:17 35:17 73:14 103:18,20 179:12	argumentative 75:15	aspects 27:15 30:7 37:21 38:2 41:5
appearing 16:6 169:22	appropriately 29:19 35:3 178:5	aristarx 36:2,7,8,9 36:21 37:2	
appears 157:22	approval 56:24 57:5,22 58:25 66:4,9 67:5,18,20 67:21 68:4,6 72:3 74:25 75:16 76:3 100:6 104:2 107:6 107:16 110:9 111:1 112:8,16 116:25 117:8,16 117:16 118:16,17 118:22 119:2,10 119:15,23 120:6 120:13 124:7 125:1 126:11,18 127:6 128:8 130:14,20,24 131:1,5,12,20,23 132:2,6 134:11 136:16,21 143:10	armsrx 37:5,6,6,9 38:12 42:15,16 46:18 157:25 170:22,25	
appended 204:7		arrangement 43:10,16 88:23 89:3	
appendix 85:24 86:12,14,21 91:10 97:15,16,17,20 98:2 99:6,10,21,22 99:23 107:4,11,15 107:18,22 108:2,6 110:10,13,14 111:3 113:13,14 114:9 115:8 135:6 135:7,11,15,22 185:21		arrangements 43:18	
appendixes 93:5			
applic 119:2			
applicable 116:20 118:13 120:4,21 173:2,5 202:8			
application 67:19 117:1,6,9 118:16 118:22 119:2,15			

[aspects - beaten]

Page 5

41:16 54:18 59:8 117:8 assessed 96:9 assessment 150:18 assigned 27:16 116:12 173:8 191:19 assignee 187:12 assignments 187:15 191:20 assignor 187:24 192:3 assignors 185:16 187:6,8,16 191:1,4 191:10,23 192:3 assistant 63:20 assisted 92:3 associated 40:10 194:22 195:25 196:4 association 2:17 10:23 46:20 47:6 47:10 49:24 50:1 50:11 185:15 assume 178:24 179:2 assumes 148:24 192:18 assuming 72:18 assurance 122:23 123:6 asthma 31:23,25 32:3 atlanta 6:11 attached 17:14 86:1 202:11 attachment 85:11 attachments 85:8 attempt 71:15 111:9	attempted 169:16 attended 65:9 attest 174:13 attesting 139:15 attorney 2:5,9,13 2:17,20,24 3:3,8 3:17,22 4:4,8,12 4:17,21,25 5:4,8 5:11,15,19,23 6:4 6:8,13,17,21 7:3,7 69:20 74:3 171:18 182:13 188:20 201:13,14 202:13 attorneys 3:12 attributed 166:22 audible 11:17 audience 82:16,19 august 200:18 aurobindo 5:8 73:6 154:17,18,20 154:24 189:20 authored 56:8,13 56:16 80:25 81:5 81:5,8,8,11,11,14 81:14,17,17 authoritative 112:11 152:20 173:13 authorization 29:13,17 35:2 authorizations 29:24 authorized 201:7 automobile 2:17 10:23 185:14 available 32:14 51:2 175:3 202:6 avenue 2:3,7 4:6 5:21 6:19 7:5 aware 49:12,22,25 51:7,13,18,19,24	91:17 138:11,20 139:24 148:1,5 154:20,22,23 155:1 160:23 165:3,22 166:16 167:1 170:5 175:5 176:13 179:3 181:13 185:9,14 b b 8:11 86:12 142:25 180:25 bachelor 18:1,9 bachelor's 18:12 18:21,24 24:25 25:19 55:12,22 back 43:3,4 59:21 60:3,5 62:8,10 67:1,2,4,24 68:1 68:25 74:18 79:15 79:18 80:2,3 92:17 93:1,25 94:2 95:2,3 99:9 101:2,3 106:16,20 108:24,25 110:20 110:22 112:1,5 120:15,17 121:23 122:12,17,20 127:15 128:22 138:19 143:20,23 154:3 156:16,22 162:12 164:21 189:14 194:6,9,10 background 34:2 95:16 97:8 100:23 101:5 bad 69:7 badger 70:1 balanced 73:9 barnes 5:9 base 60:19 61:10 61:12 103:16	172:16 based 30:12 31:4,7 31:8,16,17 32:1 49:17 59:9 74:2 86:7 89:6 104:5 104:16,22 105:2 117:4 121:12 127:13 130:22 135:10 136:18 147:1,12,13 160:24 161:2 162:15 163:15 165:21 166:11 170:4 173:15 baselessly 71:15 bases 71:20 99:1 112:18,20,21 113:1 basically 138:14 basing 134:14 147:10 basis 41:18 59:1,3 59:10,12 93:17 99:24 105:20 108:10 109:4,6 110:6 111:16,21 113:9 115:20 116:2,22 130:9 132:14 134:21 136:12 139:21 141:24 143:13 144:9,17 145:15 147:3,18 153:16 165:25 batches 154:24 160:22 baylen 6:2 bdc 163:3 bearing 72:7 beaten 173:18,22
---	--	---	---

[began - calls]

Page 6

began 29:6 36:5 behalf 10:19,21,23 10:24 11:1,5 26:18 29:15,16 32:15 40:6 69:2 69:10 73:6,23 151:25 169:22 185:6 194:20 believe 11:12 70:14 73:7 80:11 84:19 99:13 107:5 112:3 117:23 137:21 138:18 139:3 165:23 173:18 178:3 179:6 182:14 beliveau 2:14 bellevue 25:2,8 belong 93:22 94:6 129:6 ben 7:10 beneficial 22:24 23:1 beneficiaries 164:17 169:10 189:25 190:7 beneficiary 164:8 165:19 benefit 30:1 31:7 31:14 36:11,12,15 36:22 37:21,22 38:1 39:6,24 40:11 41:4,8 44:12 57:11 58:13 59:7 60:11 62:19 64:21 83:3,12 100:4 102:13,14 105:16 132:13 157:2 160:5 196:23	benefits 30:20 35:1 40:5 41:5 97:8,25 100:2 best 30:10 83:17 91:18 99:8 115:18 161:7,8 198:16 beyond 19:9 82:19 101:11 137:7,8 163:18 166:18 173:16 178:2 197:1,7 198:1,12 198:25 bio 179:6 bioequivalence 52:16 54:15,18 55:1,3,6,6,9,18 56:4 106:7 149:22 150:8,11 151:4 171:16,23 172:11 172:18 176:4,14 177:16,21,23 178:10,11,20 179:9,18 180:19 180:22 181:1 182:13,21 183:10 183:16,21,25 bioequivalent 114:21 115:11,17 150:1 172:1,15 175:25 177:7 178:4,9,25 179:7 179:12,16 180:20 180:21 181:17 biology 18:5 77:16 78:3 bipc.com 3:7 bit 16:13 66:14 154:5 186:20 blackwell 6:6 block 3:1 173:14 174:1 190:21	blocked 162:7,12 162:17,25 163:3 blocks 174:4 192:3 blvd 1:14 7:2 board 65:18 boards 105:1 bockius 5:5 body 114:22 book 81:18 100:5 101:10,16,18,19 104:3 105:17,19 105:23 107:10,12 107:17 108:14,14 109:14,21,24 110:4 112:7,9,23 115:22 116:5 119:24 120:5,24 121:3,6,12 132:10 133:10,15 134:7 149:17 152:9,17 152:21 153:7,8,17 153:20 173:6,7 178:8 181:16 183:15,23 books 81:20 bosick 4:10,14 boston 4:19 bottom 103:12 105:11 boulevard 2:11,22 10:8 bound 160:9,16 brand 66:1 67:6 112:9 114:23 127:2 133:5,6,12 143:11 144:7,14 145:24 branded 113:8,16 114:12,21 140:12 142:1,3,5,8,12,16 142:20 183:14,20	brands 30:25 53:22 break 15:10,13 59:13,19 71:2 92:16,18,19,24 128:15,16,20 153:23 154:1 189:6,12 bresnahan 5:20 brett 7:1 brief 175:17,22 189:19 bring 83:20 brisbois 3:1 broad 82:2 broadreach 22:23 28:5,9,15 29:2,5,6 29:12,21 30:5,13 brook 104:3 brought 40:25 182:5 192:21 buchanan 3:5 business 22:19,20 22:22 23:3 35:22 37:1 77:22,24 78:6,8,10,12 businesswomen's 46:20 47:6 49:23
c			
c 2:1 7:1 10:1 180:22,25 calculated 79:12 89:5,20 call 35:15 150:18 called 114:2 132:4 139:8 calling 70:2 122:2 139:5 calls 35:20 60:7 67:12 69:17 100:24 121:18			

[calls - classification]

Page 7

164:19 165:6 178:1 198:11,25 camber 3:3 camden 1:2 camp 2:19 5:17 campbell 7:4 campus 4:23 cancer 82:1,4 83:9 83:15 84:18 96:5 capacities 26:12 capacity 23:7 39:25 51:12 57:9 91:19 100:16,21 112:24 117:22 138:13 157:23,23 187:15 captures 178:3,4 179:6,11 capturing 128:2,3 carcinogen 141:1 141:2 166:23 carcinogenicity 96:10 carcinogens 93:22 96:4 145:20 cardiovascular 31:23 168:23 care 22:17,19 38:19 39:5 45:17 49:2,6,9,18 100:1 100:3 115:18 career 41:13,16 48:12 82:8,23,25 95:17,22 186:17 careful 161:3 163:12 carefully 156:10 169:4 carondelet 6:6 carrier 32:24	case 12:21 79:13 85:8 88:6,8 89:9 94:8 122:7 129:24 130:20 132:4 136:24 140:25 141:16 143:17,18 157:3 169:21 170:5 171:13 172:10 181:25 185:17 186:23 191:10 cases 35:15 102:20 196:23 categorically 71:6 categories 54:11 62:21 133:9 185:24 category 54:2,2 76:15,23 caught 16:14 197:22 caution 182:1 center 2:15 3:9 25:2,9 centre 4:10,15 5:6 cerner 2:6 certain 23:19 26:15 44:19 45:7 148:16 149:12 154:24 160:21,22 188:24 certainly 20:17 79:22 168:10 certainty 163:13 certificate 8:8,9 200:1 201:1 certificates 78:10 certification 21:15 21:19 23:10,15 certifications 21:11,12 77:17	certified 21:15,17 certify 200:7 201:6,12 cetera 11:14 31:2 80:15 cfr 178:10 cgannon 3:11 chagrin 3:16 change 150:16 153:14 203:4,7,10 203:13,16,19 changed 38:10 143:11 changes 102:10 143:9,16,25 144:2 202:10 204:6 changing 49:16 chapters 81:18 characterization 66:17 charges 88:3 charles 3:14 charlie 2:21 10:24 70:16 charlotte 3:6 chartered 2:14 check 17:6 179:24 180:5 chelsea 1:16 10:10 11:5 199:12 200:6 200:17 201:5,22 chicago 5:14 83:2 child 21:16 choice 30:24 choose 30:17 chp 194:20 chris 3:4 christine 3:9 christopher.henry 3:7	cincinnati 5:2 circumstances 150:17 cited 128:12 cites 178:8 city 2:15 civil 69:3 70:4 claim 42:25 43:23 44:16 97:22 104:19 113:23 194:23 195:23 196:4,12 claim's 162:23 claims 32:18 39:5 39:23 40:9,10,12 43:5,6,25 44:3,9 44:10 92:1 98:5,8 113:18 114:3 162:18 163:14,23 164:24 165:15 186:10 187:2,3,5 187:16 189:23 190:1,1,9,10,11,18 190:19 191:7,8,19 191:25,25 192:8 193:1,1,3,7,9,16 193:16,18,20,22 194:1,21 195:3,9 195:10,24 196:3 196:13,21 197:12 198:2,4,9,17,22 clarify 107:18 113:24 139:4 149:9 152:19 175:17 180:18 class 103:4,8 188:4 188:18 classes 20:15,18 classification 96:5 96:6,13,15 134:9
---	---	---	---

[classwork - concern]

Page 8

classwork 55:25 clear 108:17 171:19 178:20 192:17 clearly 107:17 198:4 client 23:8 28:12 28:23 30:4 38:21 44:4,5,5,6,7,11,13 57:16 58:12 59:23 60:13,19 61:10,12 61:23 82:16 102:13 158:12 160:9,11 client's 170:18 clients 30:7,17 31:14 32:15 33:6 33:10,13,14 36:23 37:20,25 38:22 41:23 42:11 56:24 57:10 58:2,3,10 59:7 62:18 82:12 82:14,19 91:18 151:25 157:15,17 158:1,4,8,13,17,20 158:23 159:19 168:6,11,14 169:6 170:17,22,25 171:3 184:14,18 clinical 23:7,7,19 24:1,23 25:1,4,6 25:13,16 26:2 28:11,12,14,18 29:12,21,22,25 31:4,6,11,11,12 33:1,20,25 34:1,21 35:16 38:20 50:24 53:19,21 83:20 103:18,22 104:6 104:16,22 105:2 126:25 152:25	155:14 clinics 25:11 close 127:23 closely 24:9 99:10 115:14 168:25 cluttered 80:4 coaching 181:21 coan 4:18 coates 4:22 coatesg 4:24 code 109:9 116:12 175:25 176:6,10 176:15 177:7,16 177:21,25 178:8 178:12,22 179:1,4 181:5,7,9,14,17 182:24 codes 109:18,20 109:23,23 116:15 collaboration 29:14,15 colleague 46:15 64:23 colleagues 36:1 collect 89:1 college 7:2 44:22 48:22,23 77:11,24 78:5 columns 125:22 combination 88:14 come 32:23 33:7 92:17 comes 23:10 comfortable 133:24 coming 15:1 27:19 27:20 152:3,7,11 152:15 comment 68:20 137:25 157:21	190:17 commented 166:22 commission 200:17 committee 41:21 42:4,20,22 102:17 102:18,22,24 103:15 104:21 118:4,5 120:20 121:5 126:11 127:16 133:7 152:8 committee's 42:6 126:6 committees 41:9 41:12,14,18,23 42:1 104:5,15 105:1 116:19 118:11,19,25 119:13 121:3,14 124:4,11 127:3 132:9,18 133:14 133:21 134:7,17 134:23 136:3 151:8,19,23 152:4 152:19 153:12 173:1 common 131:12 communicate 167:9 communicated 167:12,16 communicating 29:19 communication 64:17 communications 17:1 community 31:9 32:2	companies 159:11 159:14 160:6,17 company 36:24 42:13 79:4,7 169:20 compared 100:18 compensated 88:19 competitive 31:4 complaint 165:24 185:16,19 186:25 187:23 complete 18:8,20 86:3,14 115:15 204:8 completed 18:22 55:11,20 105:4 202:17 completely 192:20 completing 29:17 complex 34:9 compliance 22:4,6 116:20 118:12 120:3,21 127:5 132:11 173:2 compliant 124:7 132:7 complied 119:22 119:24 173:4 complying 160:10 component 58:19 115:4,6 155:20 components 31:13 54:4,19,21 133:25 138:24 computer 18:7 78:3 concept 55:6 127:10 concern 166:14
---	---	--	--

[concerning - continue]

Page 9

concerning 101:10 158:12,24 174:4 190:21 192:4 concerns 12:17 83:22 84:18 155:17 concluded 199:18 concludes 199:15 conclusion 60:7 67:13 69:17,18 70:2 74:4 100:25 121:19 122:2 130:18 164:20 165:7 178:2 187:18 conclusions 111:17,22 condition 168:24 conditions 25:25 31:10 32:4 34:9 conducted 54:10 69:7 confer 70:20 conference 12:15 confident 153:22 179:11 confidential 42:9 42:10 157:22 158:1,9,14,19,21 159:5,6,10,25 160:1 169:24 confidentiality 159:13 160:9,11 160:16 confines 40:1 confirm 86:2 conjunction 119:10 conlee 2:18 11:1 70:15	connected 201:15 connection 42:13 53:15 58:3 78:1 78:22 79:10 83:10 86:4,15,24 87:14 88:4,19 89:18 90:4,9,13,16,18 91:4,8,14,21 92:4 92:8 190:8 conservative 167:21 consider 42:22 60:24 70:11 76:12 100:22 104:24 137:13 158:8,13 158:17 159:10 consideration 57:12 58:18 60:10 75:9 76:19,19,20 106:10 115:24 116:4 119:25 126:12 131:5 135:25 136:18 150:5 considered 104:17 104:21 115:17,24 115:25 116:13,16 117:8 118:6,16 120:13,13 127:18 128:7 134:10 136:17 137:10 147:6 150:1 153:13 consistent 12:20 94:10 95:11 140:24 153:2 176:24 consistently 66:18 consists 163:23 188:4	constructed 128:1 consult 67:15 102:22 151:8 152:4,8,12,16 153:6,19,21 170:10 consultant 41:4,4 47:11 50:1,11,15 50:17,25 53:20 78:21 153:1 157:2 consultation 158:24 consulted 65:20 151:18 consulting 36:11 36:13,15,22 38:19 42:12 50:15,17 51:1,16 59:6 61:17 79:3,6,10 98:25 158:20 consults 171:12 consume 168:20 consumed 87:22 88:1,2 164:13 165:19 194:2 consuming 164:8 contact 168:5,7,8 contacted 90:9,12 90:15 contacts 165:21 contain 148:17 149:12 185:25 contained 154:25 164:8,17 165:5,19 168:19 176:14,15 177:7 190:21 containing 52:13 52:24 53:4,10 93:16 97:3,4 121:9 148:9 151:5 154:21,25 157:7	157:11,17 160:21 167:3,12 168:12 170:6 188:10 192:4 contains 105:23 125:22 contaminant 94:8 95:9 140:10,13,21 141:25 147:6 156:23 174:15 183:13 contaminants 93:16,19,21 94:5 94:14 95:8,15 96:1,3 129:10,18 129:23 130:3,6 137:3,9,14,21,22 137:23 138:1,14 139:8 141:7,10,11 141:15,19 142:3,6 143:18 145:19 146:7 147:20 155:1,3,4,6 157:4 163:24 164:3 183:19 contaminated 147:15 162:13,22 162:24 163:8 165:15 171:7,14 174:14 185:11,17 186:24 contamination 186:25 content 71:20 context 53:18 82:5 82:7 146:20,21,22 155:12 182:25 183:11 continual 152:24 continue 70:5 72:5 72:15,20 73:13,14
---	---	---	--

[continue - cwhorton]

Page 10

74:6 156:15 163:13 168:20 continues 66:20 72:19 continuing 50:20 50:22 72:11 78:7 78:9 121:25 122:3 contraindications 28:3 control 117:14 140:6 controversial 183:4 cooperative 169:17 coordination 97:25 100:2 copies 202:14 copy 40:24 85:12 85:16 113:8,16 114:11 corporation 4:8 6:21 correct 13:16 17:14,15 23:23,24 24:2,3,18 25:15 26:4,20 27:6,7,25 28:6,8 29:3 32:10 33:3 34:12 35:8 36:6 43:16,17 47:12,23 48:3 55:9 63:25 64:19 78:14 80:12,13,16 81:1,2,6,7,9,10,12 81:13,15,20,21 83:25 84:15,22 85:2,6 86:24 88:17 89:22 93:12 93:13 96:23 97:9 99:15 100:18 101:10,16 102:23	103:1 104:21,25 105:9,17,18,21,22 105:25 106:7,12 107:23 109:9,10 110:4 114:24 117:23 118:14,20 118:23 119:13 121:6 123:19 128:13 135:15 137:14 139:9 142:23 147:2 149:6,22 150:2,13 150:20 151:2 158:11 159:7 160:7 166:2 167:13 168:21 176:1,7,21 191:12 191:23 192:11 204:8 corrections 204:6 correctly 44:7 62:12 94:4,23 112:17 119:18 120:8 196:1 cost 104:4,13,14 104:18,23,24 115:19 costs 105:4 194:22 cotes 12:7,7 could've 110:15 council 35:11 counsel 9:16 10:13 10:15 17:1 22:2 27:1 69:13 70:21 71:5,14 73:16 92:12,15 111:14 181:12,23,24 201:13,15 202:14 counsel's 73:15 counseled 159:11	counseling 27:19 42:12 158:18 counselor 160:12 countless 41:17 country 160:23 161:10,24 162:9 164:13 county 200:3 201:3 couple 11:4 28:24 29:1 70:23 175:16 184:10 course 20:20 55:17 56:3 63:3,8 70:22 186:17 courses 20:21,22 20:24 55:1,3,8 63:5,11,14,19,23 63:25 64:1,2,11 coursework 20:3 55:11,20 77:10,12 77:24 78:6 court 1:1 10:10,11 10:13 11:10,19,20 12:24 13:23 14:7 14:19 68:19 69:19 74:10,12 108:23 182:9 183:7 194:5 194:8 courts 69:22 coverage 120:14 covered 30:9,9 182:11,13 covid 83:6,8 cpr 21:16 create 31:10 151:23 created 36:8 creates 30:16 credible 124:17	credits 78:8 criteria 26:16 45:7 47:8 57:5 58:24 67:20 110:4 116:3 136:16 145:22 150:19 151:14,16 164:23 183:17,19 criterion 149:16 critical 115:4 169:2 criticism 97:4 cross 8:4,6 154:14 189:21 crowell 5:21 7:5 crowell.com 5:22 7:6 crs7270 3:16 cs 202:15 culbertson 4:19 culminating 71:14 current 13:21,22 17:13,16 42:15 46:13 54:3 82:8 149:20 184:14 currently 13:24 21:5 45:2,22 79:9 curriculum 20:1 54:23 customize 102:4,9 cut 169:13 cv 8:15 17:13,14 17:16,19,21,25 23:20 28:19 30:11 31:3 32:7,25 34:11 37:14 44:18 62:2,4,14,17 63:15 64:16 80:22,23 cvs 5:11 cwhorton 2:23
--	--	--	---

[d - determine]

Page 11

d	daubert 69:22 74:10	151:5 161:11,25	department 20:9 21:18 22:11,15 23:10 63:12
d 8:1 10:1 69:3 70:12 101:15,17 106:22 143:7,13 144:4 189:23	davis 4:5	defendants 69:10 69:24 70:6 72:8 73:21 111:16 175:15 183:13 184:6,9,21	depends 43:10,15
d'lesli 4:5	day 49:13,13 86:8 86:8,18,18 91:15 91:15 100:21,21 112:24,24 115:5,5 133:22,22 152:25 152:25 155:14,14 163:22,22 172:21 172:21 185:6 200:10,12 201:17 204:15	defense 69:13 70:20 73:3,11	deponent 9:17 69:5,9 202:13 204:3
dade 200:3 201:3	days 202:17	defer 75:19,23	deposed 14:1 78:25
dallas 4:7 6:20	dc 4:2 5:22 7:6	define 77:8 115:10	deposing 202:13
dan 7:4	de 1:14 2:11,22 10:7	defined 177:24 178:12,21,25 179:4 181:4,7 182:23 183:24 188:4,19	deposition 1:10 8:14 9:17 10:6,7 14:6 16:4,7,10 17:6 66:19 69:5 71:16,23 72:5,12 73:17 79:16 181:24 195:6 199:16,18 201:8
dana 3:19	dealers 2:17 10:23 185:15	definition 34:8 95:15,21 96:1 171:15,22,25 172:3,10,17 175:25 176:3,6,13 176:14,20,22 177:7,12,16,20 178:3,5 179:6,9,11 179:12 181:9,13 181:16 183:10	depositions 11:13 11:24 12:2,4
dangerous 129:19	deals 99:15	definitions 109:8	derived 79:9
data 32:8,13,16,18 32:19,22,23 43:25 44:3,9,10,17 86:19 97:21,21 98:8 103:21 113:19 114:3 127:13 135:10 163:23 165:16 172:20 185:25 186:10,11 186:12,16,23 187:2,5 189:24 190:1,9,10,18 191:7,19,25 192:8 192:19 193:1,3,8,9 193:16,17,20,22 194:1,21 195:3,9 195:10,24 196:3 196:13,21 197:12 198:2,4,9,18,23	december 34:19	degree 18:12,21 18:24 24:25 25:7 25:20 55:12,13,13 55:21,22 78:8	describe 39:2 64:20
date 1:11 17:13 19:8 53:20 83:7,7 86:9 89:12 90:6,7 138:19 196:8,10 197:13,14,24 198:3,21 203:24 204:12	decided 103:10	degrees 19:10 77:11,20 78:5,12 115:3	description 95:7 108:14
dated 201:17	deciding 105:14	demonstrate 106:6 144:20,22	design 30:8 41:5,7 102:13,14
dates 138:23 139:3 139:5,5	decision 91:20 118:5	demonstrated 193:9	designed 31:3,7 71:8
	decisions 67:17 76:4 103:16 104:5 104:15	demonstrates 190:1	designs 83:13
	declaration 114:17	demonstrating 128:8	detail 97:22 171:18
	declare 204:4		detectable 148:17 149:13
	dedicated 38:18		determination 91:13 150:2,11,25
	deem 35:16		determine 72:25 73:1 125:21 166:7 173:4 190:6 191:3 192:2
	deemed 116:1 124:8 144:15 204:6		
	defendant 1:13 13:13 182:12 188:13		
	defendant's 71:17 140:11 142:1		

[determined - drug]

Page 12

determined 116:3	194:17	87:25 88:3 90:25	dr 10:6 13:10,20
determines 116:8	directly 22:19	95:5 101:24	27:5 44:18 59:23
149:21	44:12 173:24	112:13 125:14	68:3 69:11 70:3
determining 33:7	196:12	128:24 135:13	74:6,13,20 92:16
150:8	director 19:20	154:16 171:2	93:3 110:25
develop 101:24	23:7 28:11,17	175:21,24 177:5	111:17 140:19
102:11	29:21 34:21	177:14 179:14,22	149:15 153:15
developed 30:11	disagree 71:6	180:17 181:3	154:4 156:3
103:4,5	73:24	182:18 183:10,24	157:22 169:21
developing 30:21	disclosed 87:12	184:4 194:19	185:5 189:16
30:23	discourteous 70:4	doctorate 19:1,5,7	199:3,12
development	discovery 191:11	25:7 55:22	drew 4:1 111:23
38:20 100:2,6	discuss 109:8	document 1:6	194:19
102:20 107:6,16	110:3 126:5	16:16 40:23 90:22	drive 4:23
112:16	discussed 12:14	90:25 120:2,19	drug 22:9 26:12
developments	19:10 21:2 48:10	123:16,21 124:19	26:13,14,15 27:24
41:20	48:14 59:10 83:18	125:4,15,19,21	27:25 30:18 31:14
deviation 141:16	83:23 84:9,22	128:1,2,9 135:15	33:1,20 53:22,23
144:21	95:6 99:1 108:4	176:17,23 177:1	53:24 57:4,10,21
device 79:7	127:10	documented 31:4	60:1,10,17 61:5
diabetes 25:23	discusses 100:8	documenting	62:18,25 66:1
31:23	126:6,20	29:18	67:5,21 72:3 75:9
diagnoses 25:25	discussing 83:9,12	documents 16:22	75:16 76:3,13,21
diagnosis 32:3	83:14,24 84:8,23	17:7 40:13,16,18	82:1,3,4 83:13,13
diagram 104:7	discussion 26:11	135:4,5,7,11,22,24	83:20 84:18 100:3
105:7,11,12	26:21,23 34:4	175:5	100:3,5,6,8 101:19
diem 29:9	58:19 84:17,19	doing 73:15 82:24	101:21 102:21
differ 39:16 40:7	99:12 105:5 108:7	92:3 102:2 126:18	103:21 104:1,16
differences 39:18	dispensing 27:18	179:24,25	105:2,19,25 106:5
39:20	distance 35:5,10	dorner 4:1 8:7	107:6,15 112:8,15
different 25:25	distinction 130:1	111:23,23 194:15	113:8,8,11,15,16
30:19 35:21 39:7	distributed 188:11	194:18,19 195:1,2	114:11,12,21,22
72:21 81:23 89:2	district 1:1,1	195:7,12,22	114:23 115:6,23
91:11 109:22	division 20:22	196:18 197:2,10	116:3 118:5
129:21 139:6	63:21 64:1	197:21 198:5,14	120:11,14 121:9
157:13 167:15	divorced 192:20	199:2,4,7	121:12,15 122:23
168:11 169:16	dklinges 3:21	dosage 113:8,16	122:24,25 123:14
170:12,12 175:6	doctor 16:6,16	114:12	125:1 126:16
differs 39:12	17:25 38:17 55:13	dose 188:13	127:2,4,7 131:6,12
direct 8:4,6,7 13:8	68:8 78:14 79:15	dozens 12:8,8	131:20,21 132:3,4
185:3 192:16	80:25 81:22 85:23		132:6,13 133:12

[drug - equivalence]

Page 13

133:23 134:6,9 136:15,20 137:4,9 138:1 140:24 141:4,17 142:4 143:16 144:7,13 144:14,20 145:22 145:23,24,25 147:7 149:24,25 150:1,8 151:12,25 157:17 160:24 162:21,21 164:2 164:21 166:14 168:23 172:1 173:6,10 174:16 178:4,9 179:7,12 179:16 180:20 181:17 183:1,2,17 183:18,20 188:10 196:24 drugs 6:17 22:3 30:9,16 33:22,24 52:13,24 53:5,11 56:24 57:12 67:7 67:17,18 74:25 75:8 76:12,19 93:16 97:3,4 107:2 110:8 111:1 112:10 114:21 115:17,22,25 120:6,12,25 127:6 127:18,21 128:6 132:11 133:3,5,6,9 133:9,10,12 134:11,20 139:11 141:16 148:9 152:22 154:21,25 157:3,7,11 158:25 160:21 161:8 162:13 164:24 165:10,13 167:3 167:12 173:12	174:14 190:19 198:17 dtdorner 4:3 duane 3:19 4:1 duanemorris.com 3:21 4:3 due 93:16 duly 13:6 200:8 duties 27:13 29:11 29:13 36:20 e e 2:1,1 3:2 8:1,11 10:1,1 171:25 180:22,25,25,25 203:3,3,3 earlier 27:2 37:1 71:4 74:1 93:11 182:12 echo 186:20 economic 165:9 economics 77:7,10 77:12,18,20 education 19:9 50:20,22 54:17,22 55:2,7 59:4 77:25 78:7,9 86:8 95:17 99:21 100:15 112:23 113:12 114:14 115:3,7 132:17 133:19 135:2,11 136:1 155:21 effect 69:17 70:3 187:23 188:19 effective 58:24 104:18 114:23 115:24 116:1 117:15,18 120:25 122:23 124:8 126:8,8,17 127:5 128:8 129:20	132:8 136:22 144:15,21 145:24 163:10 173:10 effectiveness 105:20 123:14 151:17 183:2 effects 82:3,4 83:21,21 efficacy 95:12 104:13,16 149:19 efficiency 74:5 efficiently 30:1 73:13 161:16 either 44:7 102:3 111:24 196:9 elaborate 39:19 ellie 6:18 ellie.norris 4:7 6:20 embarrasses 69:8 71:9 employed 22:23 employee 23:18 42:18 201:13,14 employees 30:18 36:16 employer 23:5,6 33:14 36:14 39:8 39:13 168:7 169:22 employers 3:17 30:17,20 39:24 159:19 employment 82:10 encouraged 115:18 engaged 41:23 51:25 52:3,22 53:3,9 54:14 91:21 175:2	engagement 8:18 82:15 83:2 91:3,4 91:14 engagements 82:6 enrollment 32:9 ensure 35:2 99:11 117:17 161:17 169:10 ensuring 28:2 29:23 104:16 117:15 171:6 entail 22:1,11 24:4 55:14 entailed 30:14 32:11 55:17 77:12 entails 22:2 66:6 76:4 entire 28:16 111:12 127:12 128:1 135:10 140:16,18 178:25 entirety 81:20 99:7 108:6 110:15 111:8 164:4 entities 33:11 35:22 42:5 98:25 184:20 entitled 111:16 121:21 entity 37:4 40:6 44:13 105:14 150:7 170:23 174:10 entry 110:4 epidemic 64:18,24 epidemiology 56:9 equivalence 101:20 105:24 106:2 109:9,17,20 109:23 116:8,12 144:5 150:17,20
--	--	--	--

[equivalence - factor]

Page 14

178:8 equivalent 116:9 122:24 140:11 141:17 142:1,5 144:15 151:1 183:14 equivalents 115:17 errata 8:9 202:11 202:13,17 erratas 202:15 error 197:22 esquire 2:2,6,10 2:14,18,21 3:1,4,9 3:14,19 4:1,5,9,14 4:18,22 5:1,5,9,12 5:16,20 6:1,5,9,14 6:18 7:1,4 202:1 essential 31:13 133:25 essentially 164:5 established 58:25 68:6 74:24 75:17 110:8 111:1 112:10 120:12 128:6 134:9 140:5 153:8 et 11:14 31:2 80:15 202:4 203:1 204:1 evaluate 32:14 evaluated 20:4 150:15 evaluating 127:11 149:24 evaluation 26:11 101:20 116:8 evaluations 105:24 106:3 evasive 72:20 73:10,25	event 11:13 evidence 31:3,7,16 31:17 32:1 103:16 127:13 148:25 evolving 49:16 evp 38:12 exact 83:7 90:6,6 138:19 exactly 46:23 47:15 88:12 158:22 examination 8:4,4 8:5,5,6,6,7 13:8 70:13 154:14 158:2 175:19 180:10 182:14 184:11 185:3 189:21 194:17 examine 70:9 examined 13:6 example 195:15 196:22,24 197:4 197:15,23 examples 31:22 135:14 exceeds 89:21 excel 88:15,16 exceptions 127:21 excerpts 97:21 186:11 exchange 196:20 exchanged 196:5 196:11 exchanges 195:14 excluded 102:14 exclusive 30:12 exclusively 123:25 excuse 66:13 68:9 80:18 85:24 86:12 97:21 102:2 143:8 155:7 156:1,1	170:14 180:11,21 executive 37:10,15 37:24 38:10 157:24 executives 44:23 48:22,23 exhibit 8:13,15,16 8:18,19 16:10,13 16:15 17:14,21,24 40:14,15 79:15,18 85:13,21,23 90:23 90:24 93:4 125:10 125:11,14 126:5,6 126:12,20 127:10 127:19 128:12 195:1,5,7 exhibits 16:12 79:21 85:13 195:2 exist 39:21 expect 43:8,12,19 66:24 experience 34:2 38:18 41:9,11 43:23 54:17 59:4 59:6 86:7 98:24 99:20 100:15 107:8,24 112:23 112:25 113:12 115:7 132:17 133:19,21 134:23 135:2,12 136:1 165:21 166:1,25 168:10 172:22 173:3 expert 33:1,5,9,20 40:20,24 51:23 65:23,25 66:3,9 67:10 68:3 69:16 69:21,24,25 71:19 74:10,11 76:7,11 76:16,18 78:21,21	79:10,10,13 80:21 80:22 86:7,20 89:4,9 98:24 99:7 108:7 110:16 111:18 135:23,25 155:10 157:23 159:21 169:21 170:5 172:10,19 173:20 expertise 35:15 163:15 experts 36:1 87:11 97:21 197:9 expires 200:18 explain 88:24 explanation 108:13 109:17,20 explore 71:17 111:16,21 express 6:8 121:6 expressed 62:2,17 expressly 116:19 118:2,12,19,24 119:3,6,13,19 120:3,7,20 173:1 extensively 182:13 extent 70:13 74:7 89:2 133:13 141:14 extract 44:10 f facing 24:12 fact 98:15,16 102:19 108:10,18 109:3 113:22 114:1,7 130:23 131:11,12 137:25 149:5 162:9 163:16 186:2 factor 104:4,24
--	---	---	--

[factors - form]

Page 15

factors 104:20,22 149:23	127:6,6 128:7 130:5,25 131:6,13 131:16,19,24 132:3,5,7,11 133:16 134:11 136:16,21 138:14 139:7,10,13,14,16 139:22 140:2,5 141:13 143:17 144:2,3,3 145:23 146:6,9,12,17 148:1 149:21 150:2,9,16,24 151:15,17 152:22 153:11 155:16 157:8 161:4 162:16 163:11 164:23 166:11,13 166:16,22 168:14 171:14,15,22 172:10,17 173:8,8 174:14 175:10 176:3,10 177:25 179:4 181:16 183:20	112:25 fields 44:4 97:23 193:23,23 fifth 98:12,14 fifty 89:15,15 167:23 file 88:10 131:20 131:22 132:3 filed 132:5 165:18 185:12 files 106:5 filing 106:14 filled 27:25 filling 27:17,18 fin 114:17 finally 26:2 32:25 47:21 financially 201:15 find 64:5 126:23 findings 29:18 fine 80:7 165:20 finish 14:16,18 33:15 68:9 127:25 146:14 156:3 finished 156:6,10 184:24 186:8 188:12 firm 7:1 13:12 first 11:4 13:6,15 14:6 17:13 19:18 21:16 43:13,19 44:25 85:14 90:4 90:9 138:3,4,10,20 139:24 140:2,5 142:7,11 five 168:4 183:7 189:9 fl 1:15 2:11,23 5:6 6:3 flaherty 2:14 10:22 90:21	floor 3:10 4:10,15 4:19 florham 4:24 florida 1:16 10:8 13:23,23 37:2 200:2,7,17 201:2,6 201:23 focus 25:23 43:20 57:6,18 83:16,19 84:1,3,7 focused 58:15 folks 11:25 12:13 14:24 15:2 154:7 follow 112:10 120:11 133:6 154:5 175:17 182:10 185:1 189:19 followed 128:6 168:25 174:20 190:3 191:23 193:16 following 151:15 151:22 162:1,2,10 167:16 168:2 174:7 189:25 190:8 191:5,11 196:21 follows 13:7 food 100:6 107:6 107:15 112:15 footnote 102:19,25 123:17 124:4,10 124:20 125:4,15 foregoing 201:9 204:5 form 39:9 52:25 53:6,12 54:7,16 55:10,19 56:5,23 57:8,19 58:16 60:6,16 61:13,16
------------------------------------	---	--	--

[form - generic]

Page 16

61:25 62:15,23 65:24 66:5 67:13 74:23 75:6,14,20 76:1,9,17,25 80:19 81:3 82:13 84:10 84:25 85:4 86:17 86:25 94:7,15,21 94:24 96:14,20,25 99:3 100:24 102:5 106:13 108:10,20 109:4,13 110:12 110:23 111:5 112:6 115:2,21 116:10,24 117:5 117:12,21 118:3 120:23 122:1,21 123:4,11,24 124:2 124:22 125:6 129:12 132:16,21 133:2,20 134:5,16 134:22 135:1,18 136:9,14 137:6,15 138:12,22 140:15 143:4,15 144:12 144:18 145:12,18 147:4,14,19 148:4 148:13,19,24 149:7 150:4 152:18 159:1,18 160:8 161:1 163:18 166:19 167:4 168:13,22 169:14 171:24 172:5 174:6,22 176:2 178:1 181:6 181:11 184:1 191:13 192:15 193:15 194:24 195:19 196:16 197:5,7,17 198:11 198:24	formal 19:9 59:24 60:14,25 61:2,22 62:5,13,22,24 77:6 77:8,22 formally 162:5 format 193:17 formed 99:23 former 184:18 forming 85:7 86:4 108:6 formularies 60:11 100:4,8 101:25 102:10 103:4 151:25 162:5 formulary 29:24 30:8 31:15 33:22 33:23 34:6 35:2,3 41:5,6 54:3,5 57:1 57:13 58:19 67:17 75:9 76:4,13,20 83:13 100:2,5 102:3,4,15,21 103:5,8,16 104:17 105:14,15 115:25 116:4 118:6 120:1 120:14 121:15 126:6,7,12 127:1,3 127:7,12,16,18,21 128:5,7 132:12 134:10 136:15,18 136:19,21 147:7 151:9,15,19 152:5 152:13 153:14 157:18 158:5,12 158:18,25 159:12 160:24 161:12,25 162:4,10 164:2,22 formulating 99:17 100:11 106:23 109:11 137:12 153:5,18	forth 32:2 123:7 130:25 132:7 139:19 145:22 151:16 164:23 168:14 189:2 forward 73:13,17 151:24 found 93:18,21 137:4,14 139:22 141:4 148:8 160:21 164:4 165:15 174:5 175:25 176:6 198:4 foundation 116:2 137:6 167:4,5 178:15 181:6,18 187:1 194:25 195:20 196:17 198:13,25 foundational 115:5 founder 36:2 four 18:10 98:10 185:24 fourth 93:10 98:12 98:14 104:8 frame 25:16 26:5 29:5 37:12,16 82:22 137:1,3,5,8 137:13,20,21,22 138:7,8 150:22 151:20 161:13 162:13 164:3,4 171:6 francisco 34:14 frank 4:9 free 85:2 front 40:14,19,21 79:19 93:4	fulbright 4:6 6:19 fulfilled 55:13,21 123:13 173:9 full 13:18,20 28:20 89:25 fully 59:10 function 41:15 51:11 105:3 functions 24:6 40:10 41:7,20 49:14 91:15 100:21 104:18 115:5 128:4 133:22,23 152:25 155:15 further 8:6,6,7,7 11:3 12:6 98:1,5 154:4,6 184:9 185:3 189:15,21 191:20 194:17,17 199:7 201:12
			g
			g 10:1 ga 6:11 gain 67:21 112:8 127:5 gannon 3:9 gateway 3:9 gathering 92:4 gcoan 4:20 general 131:25 153:17 171:4 185:13 193:22 generally 195:9 generic 53:22,22 67:17,18,20 75:5,8 75:12,16 76:3,12 76:19 92:10 105:24 106:5 107:2 112:10 113:7,11,15

[generic - hansel]

Page 17

114:11,21,22 115:6,17 116:3,9 121:12 127:2,21 131:21 132:4 133:3,9,12 134:6 134:11,20 142:4 143:8,9,16 144:6 144:13 151:12 153:12 157:3 164:2 173:12 183:1,16 generics 30:25 66:1 67:6 geoffrey 4:18 geoppinger 5:1 8:5 175:16,20,22 176:5 177:3,4 178:6,18,23 179:2 179:13,21,23 180:4,11,15,16,23 181:2,12,23 182:11,17 183:9 184:4 getting 66:14 92:15 127:23 175:21 197:3 gg352672 200:18 ghansel 2:16 202:2 gisleson 5:5 8:4,6 73:5,5 154:10,15 154:16 156:1,2,5 156:12,14 157:5 158:3 159:3,7,8,15 159:22 160:3,13 161:5 163:20 165:1,11 166:20 167:7 168:17 169:8,12 170:1,14 170:18 171:1,19 171:21 172:2,8 173:22 174:2,18	174:24 175:12 185:8 188:20 189:19,20,22 191:15,16,21 192:9,16,22 193:6 193:19 194:7,11 196:14 198:10 give 13:2 15:21 16:13 31:22 65:5 115:14 125:17,24 156:9 196:22 given 56:18,21 57:6,17,20,24 59:24 60:1,9,14,21 61:23 62:5,13,22 81:25 173:8 204:9 giving 150:17 197:4 glad 182:5 glenn 2:6 10:20 12:7 gmail.com 3:16 go 11:3 14:3 15:13 16:9 17:10,21,22 66:19 68:18 72:23 72:23 74:13 85:12 90:22 99:9 114:4 114:20 127:15 128:16 138:19 153:23 156:16 162:12 164:21 180:3 181:19 goes 101:11,16 161:18 173:24 going 10:3 15:7 16:9,11,19,24 17:10 59:18 66:19 68:8,22,24 70:23 73:1 80:18 90:22 93:7,7,9 104:17 115:13 122:11	128:19 151:20 152:1 153:25 169:12,24 170:20 189:11 199:16 good 10:3 13:10 13:11 45:12,13 47:20 48:8 57:4 57:12 80:9 93:3 173:23 175:21 goodness 83:6 gordon 4:10,14 governmental 198:20 graduation 19:8 great 14:23 126:1 171:18 181:25 greenberg 2:3,7 4:23 6:10 10:18 10:20 13:13 greg 4:22 10:22 12:7,7 68:24 90:11,12 gregory 2:14 202:1 ground 14:3 69:6 70:1 grounds 16:24 group 12:5 36:15 40:6 57:18 groups 33:14 36:14 57:20 60:18 168:7 gtlaw.com 2:4 4:24 6:12 guarantee 88:25 123:6 guess 11:4 74:8 83:20 guidance 22:4 30:10 33:21 37:20 37:25 49:10,14	57:10 59:6 139:18 140:5 161:4 162:16 163:12 166:11 168:16 175:10 guidelines 31:8,16 31:17 32:1,2 48:17,24 49:3,7,20 50:2,4 51:4,8,15 51:22 103:18 124:15 182:9 h h 8:11 203:3 half 38:18 142:7 142:11 hand 12:25 200:9 200:12 handed 125:14 handle 161:9 166:15 hang 186:19 hansel 2:14 8:6 10:22,22 11:3,17 12:21 16:24 33:15 39:9 52:25 53:6 53:12 54:7,16 55:10,19 56:5,23 57:8,19 58:16 59:14 60:6,16 61:13,16,25 62:6 62:15,23 63:7 65:24 66:5,11,13 67:2,12 68:9,13,24 68:24 70:18,22,25 73:21,23 74:23 75:6,14,20 76:1,9 76:17,25 79:20,24 80:6,18 81:3 82:13 84:10,24 85:4,16,20 86:17 86:25 90:11,12
--	---	---	--

[hansel - identification]

Page 18

92:19 94:7,15,21 94:24 96:14,20,25 99:3 100:24 101:4 102:5 106:13,18 108:20 109:13 110:12,23 111:5 111:19 112:6 115:2,21 116:10 116:24 117:5,12 117:21 118:3 120:23 121:18,24 122:21 123:4,11 123:24 124:14,22 125:6,20 126:1 128:15 129:12 132:16,21 133:2 133:20 134:5,16 134:22 135:1,16 135:21 136:9,14 137:6,15 138:12 138:22 140:15 143:4,15 144:12 144:18 145:12,18 147:4,14,19 148:4 148:13,19,24 149:7 150:4 152:18 156:1,3,7 156:20 157:20 159:1,4,13,18,24 160:8 161:1 163:18 164:19 165:6 166:18 167:4 168:13,22 169:12 170:14,20 171:17,24 172:5 173:16 174:6,22 176:2 177:1 178:1 178:14,23 179:23 180:6,21 181:6,15 182:5,9 184:1,8,24 185:2,4,20 186:5,8	186:9,15,22 187:4 187:21 188:2,15 189:6,9,15 191:13 191:18 192:6,12 192:14,18 193:4 193:15 194:5,8,24 195:5,19 196:16 196:25 197:7,17 198:1,11,24 199:9 199:11 202:1 happening 49:17 86:9 happy 69:24 80:3 harassing 66:17 70:3 71:8 harassment 66:15 harkins 6:9 harkinss 6:12 haverfield 3:15 head 14:12 28:12 28:23 30:4 health 25:14,21 32:9 39:5 42:7 47:22 51:3,11 64:18 168:24 169:10 170:7 healthcare 31:8 35:12,25 39:23 44:23 45:13 46:5 46:11,19 47:6,8,9 48:22,23 49:19,23 83:3 healthy 173:23 hear 14:25,25 15:5 43:1 89:14 143:21 154:11 194:7 heard 154:17 155:10 188:23 hearing 184:8 held 10:7 19:22 34:22 37:8 59:5	heller 7:10 hello 111:23 help 31:14 helpful 156:12 186:21 helping 56:25 henry 3:4 hereto 204:7 hetero 6:17,17 hey 154:16 hi 10:24 hill 6:14 hillwallack.com 6:16 hilton 5:16 hinshaw 4:19 hinshawlaw.com 4:20 hired 155:9 hlavach 1:16 10:10 200:6,17 201:5,22 hmo 97:22 hold 19:21 25:4,16 26:5 64:22 65:13 65:22,25 66:3,9 183:3 197:2 holder 187:15 holders 143:25 holding 74:9 hollis 7:1 home 35:6,7,10 honik 6:1,1 68:18 68:19 honiklaw.com 6:3 hopefully 182:18 horse 173:18,22 hospital 23:22 24:2,11 26:1 hospitality 199:14	hour 88:22,22 89:17 hourly 88:18,18 88:21 89:7 hours 27:16 69:11 69:12 89:11,13,15 89:16 183:7 house 102:21 household 188:11 huahai 4:4 huh 13:14 14:9,14 14:14 23:12 29:8 45:15 47:4 79:17 80:13 84:6 85:25 95:9 98:20 103:14 104:9 105:8 109:16 123:18 144:11 145:4 146:3,16 151:13 177:13 human 93:22 96:4 141:1,2 145:20 166:23 humana 5:15 hundred 167:21 hurt 161:17 husch 6:6 huschblackwell.... 6:7 hypercholesterol... 26:15 hypertension 168:24
i			
iarc 96:12,15 iarc's 96:6 idea 72:15 159:10 identical 144:13 145:24 identification 16:15 17:24 85:21			

[identification - intention]

Page 19

90:24 125:11 191:5 identified 135:13 identify 97:17 158:4,11,23 159:2 159:9,16,23 160:4 160:14 161:10,23 162:9 163:16,25 164:6,12 165:17 175:6 193:20 194:2 identifying 160:17 184:13,17 il 5:14 immunizations 21:22 immunizer 21:15 21:19 impermissible 70:14 implement 173:14 implemented 166:9 174:4 190:20 192:3 importance 169:6 important 14:10 14:15 152:1 193:8 impurities 129:2,4 129:10,18,22 130:2,6,12 148:3 167:2 190:22 191:5,12 192:5 inaccurate 144:14 145:21 inappropriate 71:15 73:8 111:15 include 44:11 47:19 62:24 82:4 86:18 91:16 103:22,24 104:7 104:18 105:4,5,6	113:23 124:10 127:17 159:19 168:6 193:23 included 29:13,23 30:6,23 32:12 80:21 86:10 99:18 102:14 103:8,10 136:20 155:21 162:3 includes 27:17 30:8,25 57:9 84:17 113:20 117:8 126:7 129:1 130:11 133:11 145:23 173:10 including 27:23 32:9 39:5,24 41:5 55:23 56:3 74:7 84:18 93:15 100:15 114:14 123:13 124:12 136:1,2,25 151:17 163:24 191:22 inclusion 54:3 58:18 116:4 127:12 136:19 147:7 149:16 151:9,14,19 152:5 152:13 153:13 158:25 inclusive 201:10 income 79:9 inconsistent 95:12 143:18 incorporate 31:13 incorporated 55:3 incurred 89:2,6 90:1 indemnity 30:12 independently 96:9,11	indianapolis 5:10 indicated 159:20 183:14 indicating 193:12 indication 101:23 indirectly 196:11 individual 171:13 193:21 individually 150:12,15 169:22 individuals 38:2,4 46:3 48:7 60:18 157:13 193:21 industries 3:13 157:10 industry 30:11 36:1,1 38:19 44:3 44:10 49:15 50:24 86:19 91:17 95:16 107:9 124:16 125:2 127:4 128:2 132:1 133:23 136:2 139:7 152:20 153:2 157:14 163:15 165:21 193:17 infant 21:16 information 17:19 42:9,10 44:10,15 50:14,16,21,23,24 50:24 53:21 64:6 64:10 76:15 83:12 86:19 91:17 92:4 93:18 95:23 96:15 97:14 101:6 103:19,20 105:2 106:25 107:1,3 108:11 109:14,18 112:9 113:12,18 116:25 117:2,7 118:15,17,18,21	118:24 119:9,15 119:19 120:8,11 124:17 125:1,2 130:15,21,23 131:2,3 133:14,23 139:22 151:24 154:23 158:21 160:1 165:15,23 165:25 171:11 172:20 175:2,3,8 175:11 193:3,7 ingersoll 3:5 ingredient 188:12 initially 29:6 47:25 91:7 initiated 139:13 139:15 inquiry 103:7 insight 128:5 institute 64:22 instruct 170:20 insurance 185:15 insured 33:12,14 36:14 38:22 39:8 39:13,24 159:19 168:6 intake 166:17 167:1 168:11,19 integral 41:15 integration 32:8 intend 70:7,9 74:3 76:16 177:24 intended 26:15,16 54:1 71:25 72:2 97:6 188:10 intending 74:20 75:3,11 intends 71:21 intent 73:19 intention 73:12
--	--	---	---

[interactions - keep]

Page 20

interactions 60:22 60:25 61:7	33:18 39:11 43:3 43:7 53:2,8,14	143:6,20,24 144:16,23 145:14	113:14 114:9,10 115:7 129:18
interchangeable 129:10,17 130:6,8	54:9,20 55:15 56:1,7 57:2,14,23	146:1 147:9,17,22 148:6,15,22 149:3	ives 5:12,13
interested 201:16	58:20 59:15,22	149:10 150:6	j
interfere 15:25 71:16	60:3,12,20 61:14 61:19 62:3,8,11,20	153:4 154:4 171:18 180:13	january 1:11 10:4 188:9 200:10 201:17
interim 140:2	63:2,9 66:2,7,16	182:13 184:10,12	jason 4:14
internal 25:22	67:8,24 68:2,11,15	184:23,25 185:18	javier 7:11 10:9
international 96:5	71:5 72:17 73:22	186:4,13 187:17	jeez 20:13
interns 27:23	74:15,19 75:2,10	187:25 188:14	jeff 5:1 175:22
interpretation 85:3	75:18,22 76:6,14 76:22 77:2 79:22	189:5 199:10	jersey 1:1 3:10
interrupted 68:14 156:8	80:1,8,10,24 81:4 82:17 84:12 85:1	isidron 2:4	jgeoppinger 5:3
interrupting 180:9	85:5,14,17,22	island 19:12,19 20:7 21:3	jmistre 2:12
intimately 41:14	86:22 87:3 92:15	issue 49:20 50:2 50:12 51:4,14,21	jobs 58:4
introduction 20:20	92:20 93:2,25 94:3,12,18,22 95:2	66:16 90:18 92:1 103:8 156:24	john 5:5 73:5 154:16 189:20
investigation 190:6 191:3 192:2	95:4 96:17,22 97:1 99:4 101:2,8	159:13 169:15 173:20 181:25	john's 18:1,14 24:24 25:19
invited 46:13,14 46:15	101:12 102:7 106:16,19,21	197:9	john.gisleson 5:7
invoice 89:25 90:2 90:18,20	108:22 109:1,2,15 110:17,20,24	issued 51:8 87:14 87:16 121:3,4	join 46:13 48:7
invoices 87:14,16	111:14,20 112:1 112:12 115:9	139:10,11,14,16 139:17 157:8	joined 19:12
involve 54:17	116:6,14 117:3,10 117:19,24 118:9	163:11 166:16	jorge 2:10 11:5 26:18 70:16 199:14
involved 41:24 42:25 76:3 82:15 184:14,18	120:15,18 121:2 121:20 122:5,11	issues 158:5,18 159:12 168:24 169:5	journal 100:1,3
involves 67:18 95:23	123:1,8,15 124:1 124:18 125:3,8,10	item 80:14 98:7 107:14 110:10,13	july 93:14 97:23 186:11
involving 75:24 76:8	125:13,24 126:4 128:11,16,23	111:2 114:2 140:23 142:25	k
irbesartan 1:4	129:14 132:19,23 133:4 134:1,13,18	143:2,7,13	kali 1:10 8:3 10:6 10:6 13:5,20 200:7 201:8 202:5 203:2,24 204:2,4 204:12
irrelevant 139:3 168:9	134:24 135:3,19 136:4,11,23	items 17:23 33:2 33:20 34:5 35:16	kanner 2:18 5:17
isidro 2:2 8:4,5 10:18,18 11:12 12:6,11,23 13:9,12 17:4,5 26:23 27:4	137:11,18 138:16 139:1 140:17	80:17 97:17,24 98:12 99:10 103:24 107:22 108:1,5 110:14	kapke 5:9
			kara 5:9
			kbi 5:14
			keep 41:18 58:9 73:19 79:24 88:5

[keep - listed]

Page 21

88:9,12 keeping 49:15 133:22 kept 89:8 kerner 10:20,20 11:22 26:21 27:1 70:19,23 71:1,3 73:3,11 85:19 92:21 154:12 175:15 179:25 180:8,14 181:21 182:7 184:6 186:7 186:19 189:8,18 199:8 kind 30:19 151:23 kinds 159:11,14 klings 3:19 know 15:5,6,11,19 16:21 17:2,3 19:22 22:7 33:11 40:5 41:21,22 44:4 48:16 49:6 51:10,18,20 53:20 54:4 65:9 66:22 69:21 72:20 90:12 90:15 95:22 99:8 129:15 130:5,7 137:10 138:2,24 140:2,5 142:7,11 142:15,19 144:1 148:16,23 149:5 149:11 152:1,10 155:25 156:13 157:9 159:5 161:9 163:8 170:15 171:2,15,22 174:19 175:1,21 180:2,7 183:5 190:3,20,23,25 191:1 199:6	knowing 98:25 107:9 knowledge 95:16 99:9,20 100:15 103:3 107:8,24 114:14 135:2 136:2 148:7,11 150:10 151:3 171:9 172:15 177:22 192:10,25 198:16 knowledgeable 53:23,24 133:22 known 101:19 131:12 152:21 kristin 5:12 ks 7:2	law 7:1 13:12 69:22 law.com 5:18 lawsuit 155:9 165:18 172:19 185:12 188:21 layne 5:16 lbresnahan 5:22 7:6 lead 27:8 leading 46:4,11 49:19 186:7 187:19 learn 155:3,19 157:6 190:12 leave 35:4 80:6 left 183:6 legal 60:7 67:12 69:17,18 70:2 74:12 100:25 121:18 122:2 123:3 164:19 165:6 178:2 187:18 202:23 length 137:24 leon 1:14 2:11,22 10:7 letter 8:10,18 91:3 91:4 letting 156:13 level 168:19 levels 93:22 140:25 145:20 146:2,5,6 148:7,12 148:14 166:17,23 167:2 168:12 lewis 3:1 5:5 73:6 liability 1:4 97:25 license 21:18 22:25 23:18,18 46:2 65:12,15	licensed 21:8 46:3 48:6,7 155:13 licenses 65:13 licensure 55:23 115:3 light 12:16 likewise 32:21 limit 69:4,6 71:16 limited 74:7 182:11 limits 140:2 line 169:13 203:4 203:7,10,13,16,19 linked 31:15 linkedin 90:17 lipid 25:10 26:14 list 17:23 25:1 26:2 44:4,18 63:23 86:3,6,14 98:1 101:20 112:8 120:24 152:22 185:21 listed 17:7 25:13 37:14 43:24 44:2 45:6,10 46:1,3 47:7,18 48:6 57:22 62:1,4,13,17 63:15 85:8,10 86:21 97:14,17,20 98:19 99:23 107:4 107:5,11,17 108:1 108:8 110:10 111:2 112:8 113:13,14 115:7 115:23 116:5 119:24 122:24,25 133:15 135:5,7,15 140:24 141:17,20 145:25 173:7 183:1,22,22
	I I 9:14 180:25 I.l.c. 5:17 la 2:19 5:18 label 95:11 101:23 144:7,13,14 labeled 94:10 95:13 97:6 101:22 174:16 labels 104:1 laboratories 4:12 4:17 laboratory 20:21 laborers 3:18 labs 6:17 lack 194:24 195:19 196:17 198:24 lag 156:8 language 177:15 177:19 large 201:23 late 90:7 175:22		

[listing - materials]

Page 22

listing 132:10	144:13 151:1	making 67:16	143:8,9 144:6
lists 63:18,20	162:3,18,19	68:16 91:12,20	150:12 151:5
104:13 105:19	look 16:19,21 90:6	96:13 97:11 103:7	154:17,21 160:24
115:22 133:10,15	97:16 125:17	111:15 112:13	161:19 164:7
135:22	134:7 149:23	114:25 118:1	165:4 170:2
literature 49:14	172:10	121:5,25 123:9	183:13 196:24
91:16 103:17	looked 129:25	124:3 131:9,14,17	manufacturer's
litigation 1:5 12:3	172:3	132:25 133:19	116:19 118:12
51:15 68:4 71:21	looking 64:16	134:2 195:7	120:3,20 121:13
72:1,3 74:21 75:4	67:23 102:8	manage 25:12,24	121:13 124:24
76:8,16,24 78:20	126:22 192:16	27:15 31:14 32:7	147:1,13 162:10
78:22 79:11 86:5	looks 40:15	35:3 40:10 43:5	165:5 173:4
86:16,24 87:6,9,12	losartan 1:4 202:4	161:7,16 166:4	manufacturers
87:15 88:4,20	203:1 204:1	191:23	117:13 119:14
89:12 90:5,10,13	lot 128:5 148:8	managed 22:17	124:5 128:25
90:16,19 91:5,8,14	188:23	38:19 45:17 49:2	130:10,13,19
91:22,23 92:1,5,8	lots 148:16 149:12	49:6,9,18 100:1,3	131:2,11 136:25
92:13 100:23	186:24	171:3 189:24	144:25 145:16
106:11 111:18	louis 6:7	190:7,12 191:4,11	160:21 173:1
152:4,8,12,16	lowering 26:14	management	manufacturing
153:5,18 184:14	luke 5:20	21:24,25 22:18	172:23
184:18,21	lunch 92:16	24:1,7,10,10,10	mark 16:9,13
little 16:13 66:14	lwalsh 3:11	28:12,23 29:23,24	17:21 85:12,14
154:5	m	29:25 30:4 38:15	90:22 125:10
llc 3:8,13 6:1 36:8	m 189:23	38:21 39:5,23	marked 16:15
36:18	ma 4:19	41:6,6 64:21	17:24 85:21 90:24
llp 1:14 2:10,14,22	ma'am 197:11	100:4 102:20	125:11
3:15,19 4:1,6,10	mada 98:5,8,15	160:6	market 31:4 53:22
4:14,19 5:5,9,13	108:9,18 109:3	managing 127:16	marketed 152:22
6:6,14,19	113:21 114:2	171:4	marketing 101:22
loading 16:12	185:25 186:1,10	manner 69:7	133:17
local 3:17,18	186:23 189:23,24	manufactured	mass 6:2
lockdown 83:8	190:3,7,12,20	188:11	matches 144:14
long 18:8,20 19:12	main 149:15	manufacturer	materials 65:2
19:18,21 20:7	maine 2:17 10:23	67:19 106:5 117:1	80:22 85:7,10
21:3 66:20 72:5,9	185:14	117:6 118:14	86:3,6,9,11,15,20
72:15 92:21 97:5	maintain 160:10	119:9,22 120:10	91:7,9,12,17,22,25
137:24 185:6	major 18:4,16	123:6,13 124:6	99:6,21,22,23
189:8	majors 77:13 78:1	126:9,15,21 127:9	135:22 185:22,24
longer 70:7 72:17	78:4	131:19 132:2,5,10	185:25
72:23 73:20 144:6		140:11 141:25	

[matter - murtha]

Page 23

matter 13:2 33:1,4 33:8,20 matters 75:23 139:16 mckesson 4:8 6:21 mdl 1:4 mean 12:8 15:7 21:20 22:6,21 32:16,19 33:4,19 34:5 77:8 84:21 88:1,24 93:20 94:5 108:17 109:20 119:6 120:9 121:16 129:4 139:10,17 140:13,21 146:4 146:10 149:8 151:11 159:1 162:17,19 163:4 164:15 166:12 172:21 meaning 14:11 59:2 114:22 means 21:21 121:21 123:12 124:6 132:11 149:5 173:7,8 media 10:5 medical 22:24 25:2,9,11,23 28:5 32:2,8,14,19,23 78:14 79:7 86:23 87:1,5 103:17 medication 21:24 21:25 22:8,8 24:18,20 28:1 34:1,2,4 53:21 54:4 61:18 93:23 94:6,10 95:10 116:12 117:14,15 119:10,21,23	124:8 128:3 129:7 138:25 142:6 143:12 147:5,16 156:24 166:24 169:2 170:10 193:10,12 195:24 medications 15:24 30:24 31:1 34:6 55:5 84:17 92:11 126:8,9 127:11 133:16 143:18 146:25 147:12,21 148:2,3 153:13 155:16,16,16,17 161:20 163:23,24 170:3,6,7 173:25 medicine 25:22 meet 26:16 45:8 67:20 127:4 131:22 132:6,11 151:14 183:18 meeting 13:15 meetings 104:10 meets 57:4 58:24 116:3 150:19 151:16 183:17 member 26:3,9 36:18 42:20 44:19 44:22,25 45:2,4,16 45:19,22,24 46:4,7 46:10,13,19,22 47:5,10,13,16,21 47:24,25 48:2,4,9 48:13 51:14,21 175:2 193:10 195:23 196:7 members 61:9 103:4,8 memorized 179:8 179:10,15	mention 23:25 38:17 103:15 125:5 mentioned 16:11 21:19 22:10 23:19 32:4 43:15 54:12 98:14 106:17 107:14 154:7 mentions 125:19 143:1 meridian 5:10 merit 31:11,12 104:6,22 105:2 message 12:9 mestre 1:14 2:10 2:10,22 11:5 26:17,18,22,25 27:3 127:23 179:19 180:2,7 183:3,8 met 124:25 134:11 136:15,16,17,21 145:22 183:20 miami 1:15 2:11 2:23 10:8 200:3 201:3 middle 180:4,9 mind 72:4,7 159:2 minor 78:4 minors 18:6,18 78:2 minute 73:20 179:23 minutes 41:17,25 42:6 70:24 183:7 189:9 mischaracterizes 135:16 misheard 107:13 misrepresented 145:20	missed 99:11 missing 180:18 mitigate 169:4 mo 6:7 moment 45:8 86:2 125:17,21 127:23 156:9 177:10 184:25 money 188:10 195:14 196:4,5,10 196:21 monies 87:24 monitored 168:25 monographs 104:1 monroe 5:13 months 12:9 morgan 5:5 73:6 morganlewis.com 5:7 moring 5:21 7:5 morning 10:3 13:10,11,16 14:23 73:15,17 morris 3:19 4:1 motion 69:3 move 69:6 73:13 73:17 84:24 151:24 169:24 173:21 msp 42:22 97:21 98:15 114:6 185:15,17 186:1,2 186:11 187:5,11 187:14,22 msp's 187:6,8 191:1,4,10 192:3 mtm 21:17,23 mulberry 3:10 murtha 6:14,14
---	---	--	--

[mute - object]

Page 24

mute 186:21 mylan 4:12,12,17 4:17 n n 2:1 8:1 9:14 10:1 180:25 n.w. 4:2 name 10:9,16 13:12,18,20 31:23 114:23 143:11 144:7 154:16 155:6 159:23 163:25 194:19 name's 175:22 named 154:17 names 33:11 141:18 159:3 160:4,14,17 184:13,17 193:21 194:2 nature 41:2,3,11 50:20 169:2 navigating 100:3 nc 3:6 nda 107:2 118:14 141:21 ndc 162:20,21,21 163:3 ndcs 98:13,19 162:3,22 190:21 ndea 93:16 96:10 97:2 138:21 139:25 141:21 142:12,20 148:8 148:18 149:13 155:8 ndma 93:17 96:10 97:3 138:2,10 141:21 142:8,16 148:8,17 149:13 155:8	ne 6:11 nearby 80:6 necessarily 198:20 necessary 11:9,21 73:20 80:22 166:4 174:21 204:6 need 15:10 70:23 72:23,23 153:21 169:24 180:5 199:2 needed 22:18 29:14,16 35:15 119:23 124:25 166:6 169:11 170:7 needs 36:15 85:14 125:25 negatively 165:9 never 57:6 60:14 78:24 80:25 81:5 81:8,11,14,17 127:7 169:1 170:10 new 1:1 2:4,8,19 3:10 5:18 13:25 21:6,17 22:10,15 23:2,10,17 27:6 35:7 53:22,22 55:23 65:12 155:13 newark 3:10 nilda 2:2 10:18 13:12 nitrosamine 148:2 154:25 155:10,19 155:25 163:17 164:1,9,14,18 165:5,20 167:2 190:21 191:5,12 192:4	nitrosamines 52:1 52:4,7 56:19 140:3,6 157:7,19 160:22 168:12,19 170:6 174:5 nj 4:24 6:15 nodding 14:12 non 46:3,3 48:7 88:21 89:11,17,19 171:7,14 nonresponsive 73:10,25 nope 140:7 norris 6:18 northwell 25:14 25:21 norton 4:6 6:19 nortonrosefulbri... 4:7 6:20 notary 1:16 200:6 200:17 201:5,22 204:13,19 note 71:22 102:19 202:10 noted 27:1 204:7 notes 17:25 88:11 201:11 notice 8:14 16:7 16:10 79:16 notification 8:10 nulled 144:5 number 6:2 10:5 12:13 16:20 17:22 80:14,17 85:13 89:11 93:4 141:21 155:7 157:20 168:8 183:12 184:2 numerous 69:14 111:7	nw 5:21 7:5 ny 2:4,8 o o 3:6 9:14 10:1 180:25 oath 8:8 15:20 200:1 object 16:24 39:9 52:25 53:6,12 54:7,16 55:10,19 56:5,23 57:8,19 58:16 60:6,16 61:13,16,25 62:15 62:23 65:24 66:5 67:13 69:2 74:23 75:6,14,20 76:1,9 76:17,25 80:18,19 81:3 82:13 84:10 84:25 85:4 86:17 86:25 94:7,15,21 94:24 96:14,20,25 99:3 100:24 102:5 106:13 108:20 109:13 110:12,23 111:5 112:6 115:2 115:21 116:10,24 117:5,12,21 118:3 120:23 122:1,21 123:4,11,24 124:22 125:6 129:12 132:16,21 133:2,20 134:5,16 134:22 135:1,17 136:9 137:6,15 138:12,22 140:15 143:4,15 144:12 144:18 145:12,18 147:4,14,19 148:4 148:13,19,24 149:7 152:18 159:1,18 160:8
--	--	--	--

[object - orange]

Page 25

161:1 163:18 166:19 167:4,5 168:13,22 169:14 171:24 172:5 174:6,22 176:2 178:1,14,23 181:6 181:11 184:1 191:13 192:14 193:15 194:24 195:19 196:16 197:5,7,17 198:11 198:24 objection 62:6 63:7 66:11 67:12 68:13 84:10,24 101:4 111:15 112:2 121:18 122:1,3 124:14 125:20 135:16,21 136:14 150:4 157:20 159:24 164:19 165:6 166:18 169:12 171:17 173:16 185:18 186:4,7,13 187:1,17,18,25 188:14 189:5 191:18 192:12 193:4 196:25,25 198:1 objections 12:1,12 15:1 68:16 71:14 182:1,3 188:24 197:3 obligation 160:10 obligations 116:20 118:13 120:4,21 173:2,5 obtain 41:25 126:18 131:1	obtained 77:17,20 128:7 obtaining 74:21 75:4,12,24 obvious 107:21 occasion 172:9 occasions 69:14 82:18 occur 138:17 171:8 october 90:7 offer 36:10,12 70:6 71:21,25 72:2 74:20 75:3 75:11 76:16 offered 69:23 175:10 offering 30:18,25 31:7 68:3 71:19 76:7 92:5 97:3 official 11:19 200:9,12 oh 3:16 10:15 26:22 43:11 79:22 85:17 ohio 5:2 okay 12:21,24 14:3 15:10,14,19 16:3,6,9,19 17:10 17:21,25 19:1,6,12 19:23 20:6,15,24 21:19 23:9 24:17 24:22 25:1,8 26:25,25 27:10 28:22 29:1,4 32:7 33:17 34:13 37:4 37:18 38:4,7,9 40:2,13,21,24 41:2 44:14,18 45:9,14 46:4 47:1,5,16 48:2,16 51:20,25	57:15 61:20 62:4 62:21 79:15 80:5 80:8,11,14,25 81:17 83:9 84:21 85:12 86:11 88:18 89:5 90:4 92:20 96:18 97:2 98:1,4 98:7,21 100:14,17 101:13,15,18 105:6 106:10 107:7,10,20 108:1 108:9 109:25 110:3 112:21 113:7,25 114:2,5,9 114:20 118:18 119:3 125:9 126:2 126:24 127:8,19 130:9 132:24 133:5,8 134:14 136:12 140:9,21 141:22 145:5 147:10 148:23 150:16 156:23 162:8 177:10,23 180:15 181:20 182:20 185:2 195:13 196:3,9 197:6 199:7 once 82:20 105:3 119:21 125:23 134:8,9 166:3 one's 12:10 ones 31:20 42:8 48:10,14 61:1,2 77:15 100:13 119:19 130:13,23 141:4,6 ongoing 41:6,18 41:20 152:24 onset 87:17	op 24:16 operation 28:18 operations 23:8 28:12 29:21,23 38:16,20 opining 76:24 opinion 40:20 43:20 67:14,22 75:7 76:11,18 77:5 80:22 86:7 86:20 92:9 101:6 108:7 110:16 117:20 130:22 133:7 135:23,25 141:24 155:22 160:2 161:18 163:7 164:11 173:24 174:11 190:15 opinions 68:3 71:20,25 72:2 74:21 75:3,11 76:7,16 85:7 86:4 86:16 92:4 93:8 93:11 100:23 106:11 137:12 142:23,25 144:5 152:3,7,11,15 153:5,16,18 opioid 64:18,24 opportunity 70:20 72:7 oppresses 69:8 option 30:19 orange 100:4 101:10,16,18,19 104:2 105:17,19 105:23 107:10,12 107:17 108:14,14 109:14,21,24 110:4 112:7,9,23
---	--	--	--

[orange - part]

Page 26

115:22 116:5 119:24 120:5,24 121:3,6,12 132:10 133:10,15 134:7 149:16 152:9,17 152:21 153:6,8,17 153:19 173:6,7 178:8 181:16 183:15,22 order 67:20 127:5 130:25 149:25,25 ordinarily 186:16 ordonez 7:11 10:9 organization 22:23 23:16 38:3 40:1 45:5,20,25 46:8 47:17 48:5 48:10,13 49:19 82:15 124:16,17 organization's 47:19 64:13 organizations 44:19 48:19 49:15 51:14,21 64:18 orientation 20:19 63:8 original 72:21 137:23 143:10 144:1 156:16,19 orleans 2:19 5:18 outreach 29:15 outset 87:19 outside 59:23 60:13,18 61:11,23 62:13,21 78:5 106:10,17 137:20 158:1 169:14,17 174:23 182:3 191:13 196:21 overall 22:3,9 38:20	overland 7:2 oversee 19:25 38:2 overseeing 38:20 oversight 23:8 oxford 4:10,15 5:6 p p 2:1,1 9:14 10:1 p&2 104:10 p&t 41:9,11,14,17 41:20,22,25 42:4,5 42:20 102:16,18 102:22,24 103:15 104:5,10,15,21 105:1 116:18 118:4,4,11,19,25 119:12 120:19 121:3,5,14 124:4 124:11 126:6,11 127:3,15 128:4 132:9,18 133:6,14 133:21 134:7,17 134:23 136:3 151:8,18,22 152:4 152:8 153:12 173:1 p&ts 119:18 p.m. 1:12 74:17 92:22,25 128:18 128:21 153:24 154:2 189:13 199:16,18 pa 3:2,20 4:11,15 5:6 pachios 2:14 page 16:20 63:16 63:17 64:16 80:11 93:9 98:1,7,11 103:13,13 107:5 125:22 127:11,20 127:20 155:7,7 171:25 203:4,7,10	203:13,16,19 paged 125:21 pages 201:10 paid 65:5 146:25 147:11,15 161:20 161:21 163:8,16 163:25 164:5,16 164:21,24 165:13 165:18 170:3,4,6 173:25 174:1,13 185:10,17 186:24 187:3,5 188:9 190:2,11,19 191:7 192:1 193:2,9,10 193:13 195:10 196:7,7 197:12 198:3,21 pain 24:1,6,10 panagos 1:10 8:3 10:6 13:5,10,20 27:5 44:18 59:23 68:3 69:11 70:3 74:6,13,20 93:3 110:25 140:19 149:15 153:15 154:4 156:3 157:22 169:21 185:5 189:16 199:12 200:7 201:8 202:5 203:2 203:24 204:2,4,12 panagos's 92:16 111:17 199:3 pandemic 12:16 panel 26:3,9,10 papers 79:19 paragraph 93:10 93:12,14 103:12 104:8 105:7 111:13 112:14,18 112:22 113:2,5,7	114:20 115:1,16 116:18,23 117:25 118:11,23 119:3,7 119:12,18 121:11 121:17 123:10,17 123:22 124:3,10 124:13,20 128:13 128:24 129:5 130:10 131:10,14 131:17 132:9,14 132:25 133:8 134:3 135:9 136:5 136:6,8,13,24 140:9,14,22 141:22 143:3 145:11,15 146:24 147:11 172:25 177:11,15,20 178:7 180:24,25 181:3 182:22 188:5 paragraphs 97:8 97:12,18 99:2,15 99:18,24 100:7,12 100:18,19,22 101:9 106:22,24 108:11,15 109:5,7 109:12 110:3,7 135:14 paramount 169:6 pardon 172:13 190:24 park 4:24 7:2 part 11:15 12:15 19:16 20:15,20 28:4 29:7,9,10 30:24 31:6 34:6 44:4 49:13,15 54:18,21,23 61:9 69:4 76:21 77:11 77:13,24 101:24
--	--	--	---

[part - pharmacist]

Page 27

105:5,6,15 106:9 106:14 113:23 124:2 126:10 127:7,14 133:15 133:24 144:4 150:3,5 155:17 162:4 163:22 172:12,21 173:19 182:5,9 188:19,21 partial 156:21 participant 122:9 122:14,18 187:1 187:18 192:25 participate 24:5 26:10 participating 25:23 participation 25:10,11 particular 35:19 42:25 43:16 69:15 111:13 144:20 148:8 162:3 174:20 176:23 185:10 196:4,13 particularly 74:2 parties 9:16 69:23 201:13,14 parts 93:11 party 38:22 39:1,2 39:22 40:3,4,8 44:15 69:5,9 75:8 97:25 98:15,16 108:9,18 109:3 113:21,22 114:6 136:19 157:10 159:16,20 160:5 166:25 185:10 186:1,2 187:9,12 188:3,4,7	pass 79:18 patience 185:5 194:13 patient 22:19 24:11,12,16 28:2,3 30:7 32:3 60:22 60:22,24,24 61:1,1 61:4,6,6,17,18 162:20 163:5 164:13 168:25 171:11,12 patients 21:22 22:2 24:7,14 25:12,24 27:20 29:16 31:9 148:1 161:8,17 168:20 170:7,9,12,17,19 170:21,24 171:6 190:7 194:2 pattern 71:13 pause 16:13 26:17 pay 163:1,4,14 174:1 payer 39:1,2 40:8 payers 39:22 75:8 159:20 payment 43:8,12 43:19 88:25 165:10 192:19 payments 31:2 43:11 185:25 195:15,17 198:19 payor 98:15,16 108:9,18 109:3 113:22 114:6 157:10 159:16 186:1,2 188:4 payors 136:19 160:5 166:25 185:10 187:9,12 188:4,7	pbi 64:21 pbm 32:23 33:1,8 33:9 38:15,20 100:13 102:4 103:5,9 157:10 164:12 196:23 pbmi 64:17 pbms 33:5 42:7 99:15 101:24,24 102:11 115:18 160:15 162:12 167:1 pc 3:5 peer 103:17 pelta 7:10 pending 15:12 122:9 180:1,12 183:4 pennsylvania 5:21 7:5 pensacola 6:3 people 38:12 57:18,21 65:9 126:16 percent 79:9 percentage 79:12 perfect 6:2 perform 155:25 performance 113:9,17 114:13 performed 159:17 performing 115:4 period 28:4,20 165:13 171:8 174:3 periods 170:13 permit 70:5 permits 183:16 permitted 21:21 143:25 158:1 173:17 182:15	person 12:13 33:6 126:25 personal 64:13 88:10 130:22 166:1 172:22 188:10 personally 49:11 51:7 95:7 151:18 157:16 pertaining 87:5 158:5 pertains 78:7 104:19 108:13 133:3,5 151:24 156:25 157:15 161:7 184:2 pertinent 101:6,7 160:2 pharm 55:12 pharm.d 202:5 203:2,24 204:2,4 204:12 pharm.d. 1:10 8:3 13:5 200:8 201:8 pharma 3:13 pharmaceutical 3:13 52:20 66:4 66:10 68:5 74:22 75:5,13,25 79:4 83:10 172:23 188:12 pharmaceuticals 3:3,12 4:13,17,21 pharmacist 21:5,8 21:17,23 23:7 27:5,8,9,10,14 28:11,15 29:12 34:3 41:13 45:12 47:20 48:8 53:19 55:8 61:18 76:2 82:8 83:21 84:16
--	--	--	---

[pharmacist - prescription]

Page 28

115:4 152:25 155:13,14 157:1 171:13 172:15 pharmacists 25:24 47:11,22 50:2,12 50:18,25 51:4,11 pharmacologist 78:16 pharmacy 5:15 18:17 19:4,5,20 20:1,1,3,11,19,20 20:22 22:18,20 24:25,25 25:7,12 25:19 27:15,16,22 30:7 31:6 35:1 36:11,12,15,22 37:21,22 38:1,19 41:3,8 43:8,12,19 45:17,21 48:1,18 48:25 49:2,4,7,8 49:17,21 50:3,6,9 50:13,15,19 51:1,5 51:9 53:21 54:24 55:2,4,12,13,21,22 58:18 59:5 60:11 63:8,13,21 64:21 65:12 77:16 78:3 78:8,9 83:3,12 86:19 91:16 95:16 97:8 99:20 100:4 124:17 155:21 157:2 162:20 pharmist 29:12 philadelphia 3:20 phone 189:18 phrase 146:2 physicians 25:24 picked 11:18 128:9 piedmont 6:11	pietragallo 4:10 4:14 pietragallo.com 4:11,16 pigeonhole 111:9 pittsburgh 4:11,15 5:6 place 1:14 89:24 161:3,3,16 162:3 170:9 174:7 placed 76:20 136:15 164:22 placement 54:5 76:5,12 104:17 121:14 128:4 132:12 136:18 plaintiff 114:1 plaintiff's 71:14 92:12 98:15,16 108:9,18 109:3 113:22 114:7 186:1,2 plaintiffs 2:13,20 2:24 5:19 6:4 10:25 11:2,6 12:12,18 26:19 69:2,10,23 70:5 71:19 73:24 87:6 87:8,12 89:25 181:24 185:7,14 plan 30:8,16 41:7 83:13 132:13 193:9,13 195:10 196:7 197:12 198:3 plans 42:7 platforms 43:24 play 23:11 played 108:6 110:15	player 113:22 plaza 6:6 please 10:11,13,15 12:25 13:18 15:5 15:5 33:15 43:2,3 48:20 53:1 60:4 62:9 67:1,2,25 75:21 85:2 87:1 94:1,25 95:2 97:16 101:1,2 106:16,19 108:21 112:1,3 120:15 121:23 122:12 156:3,8,18,20 173:21 179:20 181:19 182:16,16 191:17 194:8 plus 82:24 136:1 point 80:2 99:9,11 120:2,19 134:12 142:15,19 161:14 162:14,25 163:1 172:18 190:20 192:4 195:10 pointed 99:12 points 58:6,8,9 ponce 1:14 2:11,22 10:7 populate 88:16 population 31:14 32:9 populations 26:15 portion 43:4 60:5 62:10 67:4 68:1 70:12 94:2 95:3 101:3 106:20 108:25 110:22 112:5 120:17 122:20 143:23 156:22 193:10,10 194:10	portland 2:15 position 19:21 24:4,5,13 26:6 35:4 67:9 possession 16:23 17:8 81:22 possessions 188:8 possible 42:24 44:14 83:23 84:8 102:16 possibly 163:24 172:20 post 24:16 potential 82:3 84:18 148:2 potentially 129:19 power 58:6,8,9 72:24 73:1 ppm 102:22 practice 48:18,24 49:4,7,16,18,21 50:2,5,9,13 51:1,5 51:9 103:17,18 127:4 133:23 152:20 precise 34:17 138:23 preface 107:11 prefer 140:18 178:16 preliminaries 11:4 preparing 172:3 176:21 177:6 prescribe 24:17,20 prescriber 169:1 170:11 171:12 prescribers 29:14 prescription 30:1 30:12,15,18,20 31:13 32:8,13,16 39:6,24 44:12
---	--	--	---

[prescription - program]

Page 29

57:11 58:13 59:7 62:19 76:21 100:8 102:12,12 105:16 105:24 121:14 132:13 148:2 149:25 150:8 157:2 160:5 163:4 prescriptions 27:17,18,19 44:3 189:25 190:7 presence 97:2 129:1 130:12 138:2 139:25 140:10 141:25 142:5 145:19 147:20 157:6,18 160:22 163:17 164:1,14 174:5 183:12,19 present 7:9 9:16 37:17 109:24 129:19 138:25 140:23,24 188:9 presentation 57:6 57:17,24 61:4 62:5 64:24,25 65:3,5,7,10 83:11 83:16,18 84:2 presentations 56:18,21 58:7,11 58:14 59:24 60:1 60:9,14,21,25 61:23 62:1,13,18 62:22,24 81:23,25 presented 116:25 117:1 presenter 64:17 64:23 presenting 129:1 president 37:10,11 37:13,15,24	157:24,24 preti 2:14 10:22 90:21 preti.com 2:16 202:2 pretty 173:18 preventing 130:11 previous 82:9,10 111:11 135:17 141:12 previously 154:7 primarily 35:10 36:14 38:21 82:14 104:15 primary 25:10 104:22,24 105:3 princeton 6:15 principles 77:23 100:5 princeton 4:4 prior 11:13,23 17:6 19:8 29:13 29:17,24 35:2 91:12 93:12 95:6 110:19,21 120:15 142:15,19 150:24 165:18 176:20 196:9 198:9 privilege 16:25 probable 93:22 96:4 140:25 141:2 145:20 166:23 probably 182:1 problem 12:19 72:11 procedure 69:3,16 procedures 15:16 24:7,8 process 34:3 66:4 66:6,9 67:5,7,10 67:11,18 68:4,6	72:3 74:21,24 75:4,12,16,19,24 76:2,8 100:6 106:14 107:2,6,9 107:16,25 110:8 111:1 112:7,16 120:12 126:7,10 127:1,2,3,13,14,17 128:3,3,6 133:6 141:13 152:24 153:9,22 162:23 162:23 177:6 processes 129:1 130:11 processing 40:10 42:25 43:5 112:10 producing 17:18 product 16:25 27:25,25 30:24 56:22 57:3,7,18 58:15,17,21,23,23 59:2,24 60:10,14 61:24 62:19 94:11 95:11,13 104:1 115:23 122:24,25 133:12 138:1 140:12,25 141:17 142:2,3,5,6,8,12 142:16,20 143:9 143:10,11,16 149:16,17 150:1,2 150:12,19 162:22 171:7,14 178:4 179:7,12 183:2,14 183:22 product's 150:16 products 1:4 52:20 57:11 58:17 60:1,10,17 62:25 66:1,4,10 68:5 74:22 75:5,13,16	75:25 76:3 83:10 101:20,21 105:19 105:25 144:25 145:1,17 150:8 151:1,5 153:10 155:2 160:23 161:25 163:9 172:1,23 178:9 179:16 180:20 181:17 profession 64:23 86:8 172:12,14 professional 13:21 13:22 21:12 44:19 45:13 46:2 48:6,9 48:12,13,19 51:13 51:21 52:3,23 53:9,16 54:15 57:9 65:13,18 82:7,8 84:16 91:16,19 95:17 99:20 100:16,21 112:24 117:22 138:13 169:20 186:17 professionally 73:15 professionals 35:25 125:2 128:2 professor 63:21 proffered 111:18 173:19 profile 22:4,9 90:17 program 20:1,3,5 20:11,23 30:8,12 30:15,22,23 31:2 31:11 37:21,22 38:1 41:8 54:24 55:4 57:11 58:13 59:7 62:19 63:13
--	---	---	---

[program - rate]

Page 30

76:21 88:11 programs 31:4,6 31:18 41:7 60:11 83:4 progress 20:4 41:19 prohibit 160:17 project 35:19 promise 58:23 122:22 123:5 126:15,17,21 127:9 145:21 promises 57:21 58:17 promulgated 48:18 promulgates 176:11 proof 70:6 proper 30:1 properly 22:7 proposed 103:4 111:24 188:3,18 proto 50:8 protocol 51:4,14 181:24 182:2,4 protocols 48:17,23 49:3,20 50:5 51:7 51:22 provide 22:4 33:21,23 34:3 36:22 37:20,25 42:11 49:10 50:14 51:10 115:18 117:2,7 118:15 119:9 120:11 130:15 131:1,2,3 142:22 158:20 provided 59:12 69:25 80:20 118:21 119:1,22	139:18 158:18,24 provides 128:5 providing 30:9 51:23 57:10 59:6 79:13 80:23 119:14 130:21 public 1:16 96:15 109:18 112:9 125:1 139:22 154:23 160:20 175:1,5,8,11 200:7 200:17 201:6,22 204:19 publications 56:8 56:13,16 81:15 publicized 157:9 161:14 published 52:6,9 52:12,15,18 56:11 81:9,12 105:17 pulls 59:3 punished 65:17 purported 137:14 181:9 purpose 11:15 95:21 124:12 purposes 95:14 96:19 97:18 99:12 113:21 114:11,17 123:21 135:8 pursuant 16:7 69:2 pursued 18:11 pursuing 18:23 19:6 24:24 25:7 25:19 put 161:2,3,16 162:2,15 174:7 putting 31:18 135:23,25	q qualification's 35:17 qualifications 21:12 45:7 69:12 70:8,9,13 71:18,18 71:24 72:16 74:5 74:7 qualified 69:16 quality 117:14 quarter 82:21 question 11:23 14:16,19 15:4,5,6 15:12,12 17:4 33:8,16 43:1,21 48:20 49:5 53:1 60:4,7 65:24 66:8 66:8,15,17,18,21 66:22,23,24 67:1 67:13,24 69:14,15 69:17,18 70:2 71:11,12,24,24 72:1,13,21,22 74:12 75:1 77:1,4 80:19 81:24 82:2 84:20 87:4 91:11 93:25 94:17 99:8 101:1 106:18 108:21,22,24 109:1 110:2,19,21 111:12 112:2 115:15 118:7 120:16 121:23,25 122:4,9,10,16 131:15 132:22 133:13 135:20 137:16 139:2,4,4,6 141:10,12,14 145:8 146:14 150:18 156:17,19 158:6,15 161:23	165:3 177:5 178:9 178:16 180:1,11 180:17,19 181:11 182:8,18 183:4 184:3 191:17 192:17,18,23 193:24 195:8 196:17 197:11,18 198:7,7 question's 162:8 questioned 69:11 137:23 questioning 73:7 74:4,6 169:13 170:15 182:15 questions 11:14 15:2,8,15 33:7,23 68:12,15 71:7 72:6,9,10,18 73:2 73:14 74:3 154:6 154:9,11 170:21 170:24 173:17 175:12,17 180:5,8 182:10,11,12 184:5,7,9,10,23 185:6,9 188:23 189:7,15 194:12 194:15 199:7 quick 11:22 quickly 73:18 quite 107:21
		r	r 2:1 10:1 203:3,3 r.ph 1:10 8:3 13:5 200:8 201:8 raise 12:24 raised 12:12,17 raspanti 4:10,14 rate 88:19,21 89:7 89:17

[rating - regards]

Page 31

rating 121:11 134:8,8 150:17 reach 74:4 read 16:3 43:3,4 60:3,5 62:8,10 67:1,2,4,24 68:1 93:25 94:2 95:2,3 101:2,3 106:16,20 108:22,23,25 110:20,22 112:1,4 112:5 120:15,17 121:8,23 122:12 122:17,20 140:16 140:18 143:20,23 156:22 172:17,20 194:6,8,10 199:11 202:9 204:5 reading 9:17 really 11:21 66:20 116:2 128:5 134:12 170:15 174:17 reason 12:15 14:10,14 15:20 72:10 202:11 203:6,9,12,15,18 203:21 reasonable 74:5 reasons 35:5,9 149:19 170:7 rebate 196:23 197:19,23,24 198:8,16 rebates 198:20 recall 45:8,11 55:17 56:2 64:4 83:7,14,24 84:8,23 93:15 98:13,18 125:7 139:10,11 139:12,14,15,16 139:18,23 146:21	146:22,22,23 150:24 151:22 157:8,10,11,14 160:25 161:2,7,12 161:14,17 162:1,2 162:11,14 163:11 166:3,5,6,10,14,22 167:11,16 168:2,5 168:15 169:4,5 171:3,4 173:15 174:8,20 175:7,10 185:8 189:25 190:4,8,12 191:4 191:11 194:3 recalled 98:6,8 114:3 148:17 149:12 186:10 recalls 191:4,23 receipt 202:18 receive 87:17 124:7 received 18:1 19:1 78:10,12 87:19 receiving 44:11 recitation 20:21 63:11,25 recognize 90:25 recollection 83:17 125:18 recommend 157:16 recommendation 168:15 recommendations 49:10 51:10 162:16 166:13 record 10:4 11:3 13:19 59:18,21 68:18,22,23,25,25 71:6 74:16,18 88:5,9 92:23 93:1	111:14 128:19,22 153:25 154:3 175:18 180:12 189:11,14 199:17 201:11 recorded 10:5 11:8,11,13,24 12:2 12:4 recording 11:15 12:9,20 26:20 recordkeeping 89:10 records 64:9,12,13 64:14 86:23 87:2 87:5 88:13 196:1 recovery 185:15 recross 8:5 184:11 redirect 8:5 72:8 175:19 reduce 90:1,3 reefer 4:14 refer 31:25 33:25 61:6 79:20 80:2 104:14 105:12 133:8 139:5 152:20 reference 30:12 104:14 123:16,16 124:9,11 134:12 138:19 139:13 140:24 141:9,17 145:25 173:6 183:1 referenced 31:16 94:10 95:11,12 98:12 107:12,19 115:23 122:24,25 124:19 125:4,15 139:7 141:8 146:7 146:9,12,18 155:4 174:16 177:10	183:21 202:6 referencing 119:20 120:5 referred 98:19 140:23 194:21 referring 34:10 53:25 61:7 64:13 95:23,25 109:21 110:1 111:2,3 112:7 129:21 131:25 136:6 137:1 141:3,19 146:7,17 173:12 176:23,24 195:3 196:14 197:18,19 198:9,23 refers 31:5 34:1 64:20 118:4 123:5 124:4,4 127:13 136:8,10 reflect 111:14 150:25 194:22 196:3 197:15,24 reflected 195:25 196:12 198:8,22 reflects 195:13 196:5,7 197:12 refresh 125:18 refund 164:7,13 164:15 165:18,22 185:11 188:19,20 197:16,19 refusal 160:9 refusing 160:4,12 regard 60:9 regarding 52:1,4 54:15 61:17 62:18 62:25 72:2 82:1 185:9 regards 20:2 24:7 24:8 29:25 35:1
--	---	--	--

[regards - report]

Page 32

37:21 44:9 50:14 50:25 51:11 56:25 57:21 79:13 86:20 134:20 155:24 157:3 registered 21:5,8 regulates 131:19 regulation 115:10 131:24 regulation's 179:9 regulations 95:21 95:24 115:10,14 116:21 118:13 120:4,22 131:13 131:16 132:11 135:4 173:3,5 176:1,7,9,10,11,15 177:8,17,21,25 178:13,22 179:1,5 181:5,8,10,14,18 182:24 regulatory 52:19 65:22 reimbursable 132:12 reimburse 76:21 136:20 reimbursed 147:8 165:4 193:13 reimbursement 39:4,23 104:19 reiterate 74:8 relabeler 188:13 relate 57:3 124:20 related 33:24 35:16 41:8 50:18 54:4 59:8 64:22 78:9 82:4 117:9 196:11,12 relates 1:6 55:4	relating 48:17,24 49:3,7 50:2,5,8 51:5 52:6,12,15,18 52:23 53:4,10 56:8,18,21 61:24 63:3 91:22,25 relative 201:12,14 relevant 50:17 84:19 91:17 99:13 101:6 105:12,13 relied 85:7 86:3 96:16 107:3,8 111:8,11,13 112:15 114:10 118:17,19,21,25 119:1 153:12 relies 95:22 120:3 120:20 rely 67:15,15 75:8 76:11,18 92:10 96:18 99:17 100:11 106:23 107:10 109:11 114:5,6,17 115:6 116:19 118:2,12 119:13,19 120:7 132:10 133:14 135:14 144:6 173:1 relying 95:14,20 96:6,12 97:11,14 97:18 113:1,4,15 113:20 114:25 115:3 118:1 123:9 123:21 124:2 130:17 131:7,9,11 131:13,17 132:25 133:18 134:2 135:8 remain 89:24	remaining 20:4 remember 33:15 46:23,24 47:14 122:10,15 141:18 188:25 remembers 122:14 remove 157:17 removed 160:24 161:11,24 162:5 162:10 render 67:14,22 92:9 164:11 174:11 190:15 rendered 77:5 140:10 141:25 183:13 rendering 43:21 75:7 155:23 163:7 repackager 188:13 repatha 26:3,11 26:13,14 repeat 74:1 101:1 108:21 122:3 repeated 111:9 repeatedly 69:13 70:1 71:10 84:11 111:6 124:23 repetitive 192:15 rephrase 17:4 56:12 87:4,21 129:8 131:8 137:17 141:23 145:7 150:22 158:15 report 8:17,20 17:14,18 23:25 38:3,8,12,17 40:20 40:24 76:9 79:14 80:21,23 85:9,13	86:1,14 89:4,8,9 92:16 93:4,8,10,12 94:14 95:8 96:13 97:19,22 99:5,7,14 99:19,25 100:7,12 101:15 102:20 103:1,12 106:8,11 106:17,22,24 107:4 108:12 109:5,7,12 110:11 111:3,9,12,17,22 112:14,19,22 113:2,5 114:10 117:25 118:11,24 119:4,7 121:21,22 122:7 123:2,10,23 124:3,21 128:13 128:24 129:9,16 129:21,24 130:2,3 131:18 132:15 133:1 134:3 135:9 135:10,14,23 136:8,13 137:7,8 137:13,20 138:10 138:20 139:7,11 139:24 140:8,9,22 141:20,22 142:10 142:14,18,21,22 143:3,14 144:10 145:6,10,11,16 146:24 148:10,20 155:4,22 159:21 161:15 163:7,19 164:10 169:15,18 169:19 170:16 171:10 172:4,6,25 173:17,19 174:11 174:23 176:16,21 176:24 177:6,11 177:15,20,24 178:3,7,12,21
---	---	---	---

[report - right]

Page 33

182:23 183:25 185:21,22 188:5 188:25 189:2,3 191:6 197:1,8,9 199:1,3 201:7 reported 1:16 20:2 38:5 138:3,4,5,14 143:17 144:2,3 157:18 reporter 8:9 10:10 10:11,13 11:10,20 12:24 14:7,19 68:19 108:23 183:7 194:5,8 200:6 201:1,5 reports 80:15 81:12 represent 10:17 13:13 124:5 141:16 154:17 175:23 representation 118:1 120:24 147:1,13 representations 74:2 represented 181:15 represents 121:13 122:22 124:25 198:2 request 11:10 17:2 29:17 42:2 70:6 requested 16:23 42:5 43:4 60:5 62:10 67:4 68:1 94:2 95:3 101:3 106:20 108:25 110:22 112:5 120:17 122:20 143:23 156:22	194:10 201:9 requesting 130:14 130:20 requests 16:20,25 17:8 29:14,15,16 required 22:13 24:5 45:4,24 46:10 47:5,16 48:4 55:11,20 103:15 131:2,3,5 133:24 204:13 requirement 106:9 119:25 136:17 requirements 22:12,14 23:2,17 45:6 46:1 47:18 52:19 55:14,21,24 56:3 119:23 123:13 124:25 130:25 131:22 132:7 173:9 requires 46:12 research 52:1,4,23 53:4,10 54:10,15 92:3 96:5 researched 53:15 reserved 9:18 reside 13:24 resources 22:24 28:5 respect 38:1 49:20 50:13 51:8,15,22 61:9 64:10 67:16 73:16 75:8,23 76:12 88:23 89:3 92:10 97:12 99:22 100:17 138:21 139:8,24 153:16 160:19	respected 124:16 153:9 respective 9:16 respond 71:3 166:4 responded 17:2 response 35:17 62:8 80:20 95:6 110:18,25 112:14 117:11 141:19 142:17 146:4 166:13 174:20 175:7 190:4 responsibilities 19:23,25 23:4,6 26:8 27:13 29:11 29:20,22 30:3,6 34:24 35:14 36:20 37:18,23 53:16 57:16 86:18 153:1 157:1 163:22 responsibility 40:9,11 84:16 117:17 119:8,11 120:10 126:9 155:15,18 156:25 responsible 27:24 39:4,22,25 43:11 117:2,7,13,14 128:25 130:10,15 responsive 80:17 rest 17:22 restate 48:20 49:5 53:1 75:1 94:25 109:1 139:6 156:18,20 restated 95:1 result 164:7 166:9 191:9 192:10 results 29:18	resume 17:13 retained 78:21 90:4 92:7 172:9 172:18 retainer 87:17,18 87:21,23 88:24 89:2,3,4,21,24 90:2,3 return 202:13,17 review 22:8 29:13 29:17 32:12 49:14 86:2 91:8,12,22,25 102:3 104:10 126:11 149:1 151:4 163:23 176:12,17,18,20 177:6 182:2 186:12,17 190:5,8 191:19,24 192:7 201:8 202:7 reviewed 41:17 86:7,10,12,15,21 86:23 87:5 91:9 99:6 103:17 135:5 135:23,24 176:22 177:2 185:22 190:10,18 191:7 191:25 192:8,19 193:1 194:1 195:4 reviewing 27:18 86:18 91:16 103:21 105:2 193:18 reviews 35:2 riding 173:23 right 12:1,21,25 14:8,16,21,22 16:7 16:16 18:2,12 19:13 28:1,1,5 34:15,16 36:3,4 38:6,23,24 40:14
--	---	--	---

[right - served]

Page 34

40:16,22 43:13 44:20 45:17 46:5 61:15 68:8 73:23 81:16 84:1 89:19 91:7 93:7 99:14 99:16 100:9 119:14 121:5 129:3 144:8 154:6 154:9 160:18 161:18,22 166:5 167:9 168:12 169:11 172:17 185:22 194:14,23 196:6,15,24 197:4 197:13,16,25 rights 71:17 111:21 rise 150:17 risk 40:9,12 82:1 83:9,15 rite 5:11 rivero 1:14 2:10 2:22 riveromestre.com 2:12,23 road 3:2,15 6:11 6:15 roi 31:5 role 19:18 20:16 24:12 25:8,10,21 28:9 30:21,23 32:12 34:20,22,25 35:18 38:9 41:3 42:15 49:13 53:19 59:6 63:24 64:3 82:9,9 91:16 108:6 110:15 152:25 155:14 roles 19:23,25 20:6 21:1,2 26:8 27:11 28:10,10	29:20,22 30:3,6 34:20 35:14 37:8 37:18,23 38:14 42:14 59:5 82:9 room 11:18 12:13 24:15 186:20 199:9 rooney 3:5 rose 4:6 6:19 ross 4:6 6:19 roszel 6:15 rotation 25:22 rounds 25:23 ruben 6:1,3 68:19 70:18 rule 69:3 70:12 rules 14:3 rx 34:14,18,20 s s 2:1 3:8 8:11 9:14 9:14 10:1 132:10 203:3 safe 58:24 104:18 114:23 116:1 117:15,18 120:25 122:23 124:8 126:8,8,17 127:5 128:8 129:20 132:8 136:22 144:15,20 145:24 163:10 173:10 safety 12:17 82:1 82:3 83:13 95:12 104:13 105:20 123:14 149:18 151:17 166:14 169:10 183:2 sale 133:16 sameness 182:25 san 34:14	sanctioned 65:17 sarah 6:5 sarah.zimmerman 6:7 savage 3:15 saying 14:11,12,20 84:3 118:23 149:4 169:9 says 97:22 98:5 119:12 183:12 schaffer 3:14 school 45:21 48:1 sciegen 4:21 science 18:1,7,9 78:3 sciences 20:9,22 63:12,22 scientific 103:16 scope 49:9 94:8 95:17,22 100:20 106:8,11,17 129:24 133:7 137:7,8,20 140:7 142:9,13,17,21 148:10,20 155:22 157:1 158:1 160:2 161:15 163:7,19 164:10 166:18 169:14,18 171:10 172:12,14 173:16 174:10,23 176:16 178:2 182:2,15 188:25 189:2 190:5,14 191:6,14 191:24 194:15 197:1,8 198:1,12 198:25 scripts 6:8 seal 200:9,12 second 18:11 144:4 156:4,7	186:19 section 93:10 97:7 97:7 99:14 100:7 101:15,17 106:22 127:12,15,16 141:20 142:22 143:7,14 144:4,9 144:24 145:9 155:5,7 171:25 sections 99:11 127:17,19,20 see 11:7 12:19 14:7 40:13 72:10 104:11 119:3 189:6 193:17 seek 190:12 seeking 110:8 111:1 117:16 119:10,15 126:10 131:20 132:2,6 185:11 seen 14:23 16:16 195:2 self 33:12,14 36:14 38:22 39:8,13,24 159:19 168:6 sending 90:19 senior 37:10,12,19 38:5,10 157:24 sense 158:16 181:4 sent 202:14 sentence 96:3 119:17 140:16,18 143:20 183:12 september 90:8 series 185:15 serious 168:24 serve 101:5 served 20:8 32:25 33:4,8,19
---	---	--	--

[serves - standing]

Page 35

serves 183:15	83:21	sound 100:5	129:15 131:21
service 196:8,10	sign 16:3 199:11	source 112:11	184:3 188:7
197:13,14 198:3	202:12	152:21 153:10,11	specificity 102:8
services 19:20	signature 200:16	173:13 183:15	specify 151:20
28:23 30:4 34:21	201:22	south 3:20 5:10	speculate 103:11
36:9 38:21 63:12	signed 202:20	6:2	138:7,23 148:21
serving 170:4	significance 109:8	speak 126:14	149:1,4 162:6
set 32:2 35:1 123:6	signing 9:17	157:13	163:6 176:19
130:25 132:7	similar 129:25	speaking 68:16	190:17
139:19 140:2	198:19	71:13 82:5,15	speculation
145:22 151:16	simple 174:17	83:3 84:17 111:15	198:12,25
164:23 168:14	single 12:10	112:2 181:25	speeches 81:25
189:2 196:13	125:22 158:17	197:3	spend 88:5,7 93:7
setup 12:16 14:25	165:17	speaks 76:10	spent 34:13,18
seven 183:7	sit 55:16 56:2	126:12	88:9 89:6,8,12
shape 173:24	site 47:19 48:6	special 23:23 24:2	split 29:4
share 58:10 103:3	51:2	specialty 33:2,20	spoken 57:20
sheet 8:9 98:15,16	six 12:9	34:5,6,8 53:23	60:17 82:2,18
108:10,19 109:4	smith 34:14,18,20	specific 31:17	87:8,11 92:12
113:22 114:1,7	social 20:9,22	33:10 39:10,17	spreadsheet 88:16
186:2,3 202:11	63:12,21	42:8 43:14 53:13	spreadsheets
shenandoah 19:2	society 47:22 51:3	54:8 58:12 66:12	98:10
shift 27:23	solco 4:4	67:17 71:25 72:2	st 6:7 18:1,14
shoes 187:23	sold 188:12	75:21 87:1 95:20	24:24 25:19
short 103:7 189:6	sole 36:18	95:24 102:6	staff 23:18 27:9,10
shorthand 200:6	solutions 202:23	103:21 107:1	27:14
201:5	somebody 186:20	127:8 131:13,16	stakeholders
shortly 28:25	someone's 16:11	131:24 134:6	105:12,13
show 63:18 126:20	sorry 10:16 54:21	135:4,13 138:5,8	stand 73:25
127:10 177:1	60:3 61:11 85:15	141:2,9 148:14	standard 44:3
186:23 187:5	85:17,20 89:14	151:10 162:8	193:16
showed 187:2	96:23 107:13	171:11 176:8	standards 48:17
190:10,19 191:7	108:22 127:21	182:12 193:5,20	48:24 49:3,20
showing 185:25	141:9 143:22	193:21,24 196:20	50:8 51:4,8,15,22
shown 181:8	146:13,15 156:5	197:4	69:21 74:11
shows 190:1	156:15 176:25	specifically 55:8	103:16 116:20
191:25 193:1	180:4 194:4	55:16,17 56:3	118:13 120:4,21
sic 64:21	sort 24:12 50:12	58:15 67:16 82:11	173:2,5
side 22:19,20,22	sought 164:7,13	83:14,24 84:7,23	standing 45:12,13
32:13,14,17,20	165:4,17,22	93:9 96:2 97:9	47:20 48:8 54:3
73:3,11 82:3		110:18 116:7	56:24,25,25 57:4

[standing - sure]

Page 36

57:12 standpoint 165:9 stands 187:23 start 14:17,18 48:21 92:15 167:8 started 74:14 92:18 starting 29:1 state 1:16 4:19 10:14,15,16 13:18 21:6,9,18 22:10,15 23:2,10,17 55:23 64:17 71:5 93:14 102:25 113:7 115:16 116:18 121:11 128:24 132:9 136:24 140:9 143:7,8 144:5,24 146:24 155:13 200:2,7,17 201:2,6,23 stated 93:8,11 94:23 108:11 statement 40:20 93:17 96:7,13,16 96:19 112:18,22 113:10,15,21 114:11,18,25 115:20 116:22 118:10 120:9 123:22 124:3,20 128:13 130:9 131:10,14,17 132:14,25 133:19 135:8 136:12 137:2 139:21 143:13 144:4,9,17 144:24 145:6,15 147:3,11,18,24 statements 50:12 71:4 73:24 74:1	97:11 99:2,18,24 100:12 101:10 109:4 110:6 111:17,21 112:13 113:2,4 121:6 123:9 134:3 states 1:1 28:19 30:11 31:3 32:7 32:25 69:4 101:22 118:24 120:13 121:1 133:11,17 133:17 150:9 152:23 161:24 164:7 165:4 188:8 stating 130:17 131:7 145:22 status 12:14 98:13 98:19 104:2 120:6 stay 86:8 staying 53:20 steamfitters 3:17 stenographic 68:25 201:11 stenographically 69:1 201:7 step 70:25 steps 150:25 steven 6:9 stipulate 111:10 111:19,20,24 121:24 122:2,5 stipulated 9:15 stipulation 111:25 stop 68:8 148:3 169:2 170:10 stoy 4:9 strategic 35:11 strategies 128:4 161:2,3,6,16 162:2 166:9 170:9 175:6 191:22 192:7,11	strategy 151:23 152:1 162:15 163:12 166:7 168:15 170:8 174:7,8,19 190:3 190:18 192:20,24 street 2:19 3:5,10 3:20 4:2,19 5:2,10 5:17 6:2 strike 84:24 163:2 168:3 191:2 structure 31:12 43:10,15 57:11 structured 30:19 31:1 student 20:2,4 students 20:2 60:23 62:25 studies 80:15 81:9 95:17 103:22 151:4 172:21 study 99:10 115:12,13 studying 55:5 subformularies 127:21 subject 33:1,4,8 33:19 149:17 186:25 submissions 144:1 submit 131:11 submitted 104:1 117:6 118:22 143:19 144:3 150:14 submitting 130:13 130:19,23 subscribed 204:14 subsequent 196:10 197:24 198:8	subset 30:16 subsidies 198:20 substance 94:5,9 95:9 129:6 substitutability 134:8 144:19 152:21 183:16 substitutable 115:25 116:13,16 153:11 substituted 116:9 substitution 115:16 suffice 126:18 sufficed 55:24 124:7 164:22 173:9 suffices 119:25 sufficient 162:14 suggest 72:4 suggestion 71:7 suing 187:14 188:19,20 suitable 132:12 170:11 suite 1:14 2:11,22 3:2,5 4:2,6,23 5:2 5:13 6:6,11,19 7:2 10:8 summary 142:22 142:25 144:5 supervise 27:21 supervision 27:23 support 117:11 128:12 sure 14:5 16:5 17:11 26:19 31:6 48:21 53:3 59:15 70:25 84:4 93:24 94:19,25 106:19 109:19 118:10
---	---	---	--

[sure - tier]

Page 37

137:16 149:8 154:8 156:9 158:22 167:18 193:7 194:1 195:21,23 196:22 surgery 23:23 24:2,14,15 surrounding 155:17 169:5 surveys 35:16 suspend 71:22 suspended 65:15 swear 10:12 13:1 swedesford 3:2 sworn 13:6 200:9 204:14 system 51:3,11 126:7 systems 47:22 126:7 127:16	talking 61:11 131:21 180:23 196:14 talks 97:7 127:11 tasked 150:7 taught 20:19,20,24 63:3,5,24 64:3 te 109:23 teach 20:15,18 team 24:9,10 teams 25:12 technicians 27:21 tel 4:20 tell 30:13 31:5 32:11 44:15 103:9 ten 56:14 72:21 167:25 tend 34:8 term 34:11 58:21 59:2,11 93:19 94:5 95:7 96:1 115:11 121:16,20 122:6 123:2,3,5 129:4,22,23 130:2 130:3 136:5,6,7 139:17 140:13,21 143:1,1 145:5,6,9 177:23 178:10,11 179:16 180:19,20 terminate 69:4,6 70:12 71:15 terminus 6:10 terms 32:1 54:5 62:18 95:25 113:8 113:16 114:12 129:9,16 130:5 134:11 146:8 153:10 168:15 territories 188:8 territory 66:15	tested 142:8,12,16 142:20 testified 13:7 78:24,25 111:7 179:3 181:13 testify 15:19,25 159:4,14 testifying 88:21,22 89:11,17,19 169:17 170:22 testimony 8:3 13:1 15:21 51:23 79:10 80:16 111:11 135:17 177:19 195:24 198:10 202:9,18 204:8 teva 2:5,9 3:12,12 6:13 10:19,21 13:13 texas 4:7 6:20 thank 12:23 13:24 27:3 33:17 59:16 70:18 74:14,15 80:9 95:14 122:13 122:18,19 125:12 156:11,21 175:13 180:15 183:8 184:4 185:2,5 189:16 194:11,12 194:14 199:12,14 thanks 156:12 199:13 therapeutic 54:2 101:20 105:23 106:2 109:8,17,20 109:23 116:7,12 127:22 150:16,19 178:8 therapeutically 151:1	therapy 21:24,25 thereabout 138:18 thing 70:19 73:12 74:8 132:24 136:7 143:21 things 22:22 106:6 111:8 129:18,22 198:20 think 11:8 34:19 61:22 72:15 83:7 92:21 107:13,19 108:23 135:13 158:6 168:8 171:19 179:3 180:18 197:19 thinks 156:9 third 38:22 39:1,2 39:22 40:3,4,8 44:15 75:8 97:25 98:15,16 108:9,18 109:3 113:21,22 114:6 136:19 157:10 159:16,20 160:5 166:25 185:10 186:1,2 187:9,12 188:3,4,7 thornburg 5:9 thoroughly 71:17 173:18 thought 34:3 107:14 156:5 thoughtful 115:15 161:3 163:12 threatened 71:22 three 3:9 114:9 tie 170:16 tied 42:11 44:12 50:25 58:12 63:25 67:19 76:4 102:14 tier 104:8 105:11
t			
t 8:11 9:14,14 180:22 203:3,3 take 14:20 15:7,10 16:19,21 18:8,20 22:7 30:20 55:1 59:13 66:16 80:3 84:21 86:2 128:15 128:16 150:25 153:23 169:11 173:4 189:6 taken 1:13 55:8 59:19 71:2 92:24 128:20 135:24 154:1 168:23 181:25 189:12 takes 30:16 67:10 125:20 talk 14:15 17:12 83:20 97:9			

[tiering - uh]

Page 38

tiering 31:2	title 19:24	174:21 175:3	traurig 2:3,7 4:23
till 19:17 37:17	titled 101:15	195:16,17,23	6:10 10:18,20
time 1:12 12:10	104:10	196:23	13:13
13:15 14:21 15:4	titles 20:6 21:2	tpp's 153:16	treat 73:16
15:10,18 18:18	58:11 63:5,14,18	195:25	treated 31:9
22:12 24:22,24	63:23 64:2	tps 38:22 41:2	treatment 32:3
25:4,6,16,18 26:5	today 15:2,17,22	67:15,15 75:7	trial 78:25
27:8,16,22,24 28:4	16:6 17:6 40:25	76:11,18 92:10	tried 170:15
28:16,20 29:2,4,5	43:21 48:2 55:16	97:9,13 102:3,10	true 201:10 204:8
29:6,7,9,10,10	56:2 67:14 71:8	102:12 116:18	trust 185:15
30:13 34:17 35:7	89:7 157:22 163:8	118:1,11,19,25	truth 13:2,3,3
35:19 37:12,15	188:23	119:12,18 121:14	153:10,11 183:15
46:16,25 55:5	today's 199:15	132:10 133:14	truthful 15:21
59:17,20 64:4,9,12	told 90:17 181:7	146:25 147:11,15	try 14:17 178:19
64:24 66:20 68:21	183:24 192:19	152:12,19 160:15	trying 14:19 23:9
69:5 70:7 72:5,12	tone 73:8	161:19 162:12	83:6 137:19
72:14 73:22 74:17	top 103:13	163:8 164:21	170:16
82:22 88:5,7,9,12	topic 57:18 58:15	165:8 166:4,9	turn 79:15 85:23
89:6,8 92:17,18,22	169:25	167:9,12,15 168:4	93:9
92:25 93:7 115:13	topics 70:8 188:24	168:6 169:9 170:3	turned 145:1,17
121:24 122:4	torts 6:2	170:5 171:2,4	two 19:8 21:1
125:24 128:18,21	total 89:5,11	172:25 173:3,14	38:13 62:21 69:11
137:1,3,5,8,9,13	touch 108:16	173:24 174:4,7,8	69:12 98:18
137:20,21,22,24	toxicologist 78:18	174:13 175:6	107:22 108:4
138:7,8 150:22	toxicology 155:20	184:14,18 187:24	141:18 144:11
151:20 153:15	tp 102:2	192:3	type 20:21 23:3
156:7,23 160:20	tpa 40:2,9 42:24	track 41:18 88:7	26:13 30:15 33:11
161:13 162:13	43:9,13,19,24 44:7	88:12	50:16 186:16
164:3,4 165:13	44:16	tracked 88:14	198:8,17
169:5 171:6,8	tpas 43:5	tracking 29:18	types 22:22 35:22
174:4 175:13	tpp 38:25 39:7,12	88:3	50:23
178:25 179:19,24	40:7 42:18,22,25	trade 3:5	typical 193:17
180:2,5 182:19	43:9,24 44:8,16	training 77:6,22	u
183:6 189:10,13	97:8 102:16,21	transaction	u 9:14 180:25
194:13,23 195:14	103:4,7,10 120:2	194:22 196:5,6	u.s. 4:4 100:5
196:6 199:16	147:8 152:16	transcript 201:9	107:5,15 112:15
202:19	153:6,19 160:23	201:10 202:6,20	uh 13:14 14:9,14
time's 180:6	161:10,23 162:9	204:5,8	14:14 23:12 29:8
timeframe 202:8	163:1,4,16,25	transition 170:11	45:15 47:4 79:17
times 57:24 82:20	164:2,6,12 165:3	170:12 171:7,8,13	80:13 84:6 85:25
82:20 111:7	165:17,22 174:20		95:9 98:20 103:14

[uh - videographer]

Page 39

104:9 105:8 109:16 123:18 144:11 145:4 146:3,16 151:13 177:13 ulmer 5:1 ulmer.com 5:3 ultimate 40:8,11 ultimately 43:11 unacceptable 68:14,17 70:11 93:21 129:2,2 130:12 140:25 145:19 146:2,5,6 166:23 170:17 unbiased 105:1 unclear 178:16 197:18 understand 14:13 15:4 23:9 24:6 54:1 58:21 66:6 66:22,23 76:2 77:4 84:3 93:19 94:5,25 95:5 106:9 109:19 110:2 112:14 118:7 123:3 127:2 129:8 131:15 133:13 137:16,19 141:14 155:15 156:25 158:6 166:6 170:8 176:25 182:2 187:8,11,14,22 188:3,18 196:9 understanding 11:16,23 12:5 41:15 44:6 59:1,3 59:10 62:12 67:6 67:9 80:16 84:4 84:15,22 94:4,19	95:25 107:25 112:17,17 113:11 115:5 119:17 120:8 128:25 130:11 131:25 132:1 134:17,21 139:12,20 165:8 165:12 166:8 174:3 176:17 188:16 189:24 191:10 196:1 understood 15:7 93:24 168:18 underwriters 64:18 83:3 unfair 111:10 unfamiliar 54:25 unfortunately 71:10 unit 10:5 united 1:1 101:22 120:13,25 133:11 133:16,17 150:9 152:23 161:24 164:6 165:3 188:7 universal 34:7 174:8 university 18:1,14 19:2 20:7 21:3 25:14,19 university's 19:13 19:19 unjustly 161:20 170:3 173:25 unreasonably 69:8 update 179:19 updates 17:19 41:7 53:21,21 uphold 126:10	upholding 78:8 upkeep 86:8 usa 3:12 use 26:11,16 34:1 34:10 54:1 58:6 60:2,18 88:11 97:6 102:16,21 120:25 122:6 123:2 129:9,22,22 130:1,2 136:6,7 145:1,5 146:8 152:9,10,16 153:6 153:8,17,19 177:24 179:22 181:3 182:21 188:11 uses 121:22 136:5 utilization 41:6	vanderbilt 2:3,7 varies 67:5 various 57:10 101:9 185:21 vast 181:9 vauggn 7:1 vcd 138:3,11 162:10 163:16 164:1,8,14,16 165:5,19 175:7 189:25 190:4,8 191:4,11 vcds 136:25 138:21 139:9,25 140:11 142:1 161:11,19 162:25 163:1 167:17 168:5,12,18,20 169:11 170:3 173:14 174:4,20 183:14 190:13,21 192:4 194:2 verbal 57:17 verbally 14:11 verbatim 126:22 verify 202:9 verifying 28:1 veritext 10:11 202:14,23 veritext.com 202:15 versions 140:11 142:1 183:13 versus 103:5 130:2 vice 37:10,10,12 37:15,24 157:24 157:24 vicinage 1:2 video 10:5 11:18 videographer 7:10 7:11 10:3,10,15
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[videographer - x]

Page 40

11:9,19,19 59:17 59:20 68:21 74:17 92:22,25 128:18 128:21 153:24 154:2 189:10,13 199:13,15 videotaped 1:9 view 73:9 130:7 160:16 views 130:5 violation 150:18 visibility 41:22 visit 24:16 voluntary 93:15 157:11 vp 37:19 38:5,10 38:10	136:5,6,25 warranty 58:23 121:13,16,25 122:4,6,22 123:2 126:15 136:7 143:1,1 144:25 145:5,7,9,16 161:19 170:2 washington 4:2 5:22 7:6 way 23:1 38:9 54:23 65:18 71:9 73:8 91:11 95:1 103:9 114:22 139:6 143:2,9 145:7,10 147:8,24 148:23 149:5,8,11 161:8 167:19 171:5 182:3 wayne 3:2 ways 39:12,15 72:21 169:16 we've 19:10 21:1 48:10,14 80:19 108:4 135:13 webinar 65:7 webinars 64:22 website 45:6 46:2 46:3 47:7 93:18 139:22 146:19 welcome 80:3 175:14 189:17 wellness 36:2,7,8,9 36:21 37:2 went 82:19 162:20 west 3:5 wharton 2:21 10:24,24 43:1 whiteley 2:18,18 5:17 11:1,1 70:17 72:13	whiteley's 74:3 wholesaler 188:13 widely 153:9 william 6:14,14 windermere 13:23 wise 40:23 wish 167:20 190:17 withdraw 122:6 withdrawn 56:11 63:4 81:23 102:2 124:9 149:18 witness 10:12 13:4 17:1 33:17 59:13 59:16 66:18,21,24 68:14 69:15,16,20 69:20 70:1,8,10 71:9,10,23 72:6,18 72:19,22 73:9,16 73:19,25 78:21 80:7,9 111:7 122:10,13,17,19 125:12 126:2 154:13 156:18 157:23 169:16 170:21 175:14 177:2 178:24 181:20,22 189:17 194:14 195:2 197:6 200:9,12 202:8,10,12,19 witness's 73:1 witnesses 69:21 74:11 wmurtha 6:16 woman 47:9 women 46:4,10 49:19 word 12:10 88:1 94:13 119:3,6 125:22 155:10	178:20,24 179:4,9 179:9,10,11,18 180:23,24 181:3 182:21,22,23,25 188:20 words 126:22 127:8 work 15:16 16:25 24:9 27:17 41:2,3 57:16 59:23 60:13 60:23 61:23 62:24 79:3,6 82:24 87:15 88:21,22 89:19 90:19 98:25 114:22 134:17 157:1 158:5,12 159:17 160:6,15 169:23,23 191:9 worked 27:5 28:5 46:15,17 65:20 184:20 workflow 30:2 working 27:21 38:21 works 14:4 107:9 107:25 world 49:18 126:16,21 127:9 138:14 139:8 wrap 182:16 199:2 writing 17:3 written 80:20 88:11,14 147:25 182:22 wrong 85:2 www.kanner 5:18
w			
w 5:13 wait 14:16,18 waive 111:20 walgreens 27:6,11 29:5,10 wallack 6:14 walnut 5:2 walsh.law 3:11,11 walter 3:15 want 16:3 73:4 74:8 79:20 84:4 90:7 93:24 94:19 95:5 156:16 157:21 158:7 175:17 180:2,17 wanted 26:18,19 71:11 169:9 wants 174:19 warranties 52:10 56:22 57:3,7,18 58:15,17,22 59:2 59:25 60:15 61:24 125:5,19 126:5,14			
			x
			x 8:1,11

[yeah - zooms]

Page 41

y	zooms 11:12
yeah 12:11 33:9 34:19 36:1 46:9 50:15 71:1 73:5 85:19 97:20 98:17 114:16 127:25 138:23 181:23 189:19 197:22 year 20:12,12 28:14,14,17,17,22 28:22 34:13,14 46:23 82:20,20 years 18:10 19:8 28:24 29:1 38:18 47:3 56:14 59:4,4 59:5 82:24 136:1 yep 23:21 142:24 york 2:4,8 13:25 21:6,18 22:10,15 23:2,10,17 27:6 35:7 55:23 65:12 155:13	
z	
zhp 3:22 4:4 111:23 zimmerman 6:5 zoom 3:3,8,13,18 3:22 4:4,8,13,17 4:21,25 5:4,8,11 5:15,19,23 6:4,8 6:13,17,21 7:3,7 7:10 11:7,8,10,14 11:15,24,25 12:2,4 12:16,20 14:24 15:1,3 16:11,12 26:20 122:9,14,18 154:8 175:15 184:7 186:21 187:1,18 199:8	

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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Exhibit 52

Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
MDL NO. 2875

-----X
IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

THIS DOCUMENT RELATES TO:

All Actions

Case No. 1:19-md-02875-RBK-SAK
-----X

VIDEO DEPOSITION OF : RON NAJAFI

February 3, 2022

* * * * *

TRANSCRIPT of the videotaped deposition of the
above-named witness, called for Oral Examination in
the above-entitled matter, said deposition being
taken pursuant to Superior Court Rules of Civil
Practice and Procedure, by and before MICHELLE L.
DAWKINS, CSR, RPR, a Certified Court Reporter and
Notary Public of the State of New Jersey, held
REMOTELY VIA ZOOM on Thursday, February 3, 2022,
commencing at 9:09 a.m. Pacific Standard Time.

<p style="text-align: right;">Page 2</p> <p>1 A P P E A R A N C E S :</p> <p>2 For the Plaintiffs:</p> <p>3 KANNER & WHITELEY LLC</p> <p>4 BY: LAYNE HILTON, ESQ.</p> <p>5 DAVID STANOCH, ESQ.</p> <p>6 CONLEE SCHELL WHITELEY, ESQ.</p> <p>7 701 Camp Street</p> <p>8 New Orleans, LA 70130</p> <p>9 504.524.5777</p> <p>10 l.hilton@kanner-law.com</p> <p>11 d.stanoch@kanner-law.com</p> <p>12 c.whiteley@kanner-law.com</p> <p>13 LEVIN PAPANTONIO THOMAS MITCHELL</p> <p>14 RAFFERTY & PROCTOR P.A.</p> <p>15 BY: DANIEL NIGH, ESQ.</p> <p>16 316 South Baylen Street</p> <p>17 Pensacola, FL 32502</p> <p>18 850.435.7013</p> <p>19 dnigh@levinlaw.com</p> <p>20 LEVIN SEDRAN & BERMAN LLP</p> <p>21 BY: CHARLES E. SCHAFER, ESQ.</p> <p>22 510 Walnut Street - Suite 500</p> <p>23 Philadelphia, PA 19106</p> <p>24 215.592.1500</p> <p>25 cschaffer@lfsblaw.com</p> <p>SLACK DAVIS SANGER LLP</p> <p>BY: JOHN R. DAVIS, ESQ.</p> <p>6001 Bold Ruler Way - Suite 100</p> <p>Austin, TX 78746</p> <p>866.531.2048</p> <p>jdavis@slackdavis.com</p>	<p style="text-align: right;">Page 4</p> <p>1 A P P E A R A N C E S (Continued):</p> <p>2 For the Defendant, Cygnus Pharmaceuticals, Inc.:</p> <p>3 HINSHAW & CULBERTSON LLP</p> <p>4 BY: GEOFFREY M. COAN, ESQ.</p> <p>5 53 State Street - 27th Floor</p> <p>6 Boston, MA 02109</p> <p>7 617.213.7000</p> <p>8 gcoan@hinshawlaw.com</p> <p>9 For the Defendant, Camber Pharmaceuticals:</p> <p>10 LEWIS BRISBOIS BISGAARD & SMITH LLP</p> <p>11 BY: ASHER A. BLOCK, ESQ.</p> <p>12 500 East Swedesford Road - Suite 270</p> <p>13 Wayne, PA 19087</p> <p>14 215.977.4066</p> <p>15 asher.block@lewisbrisbois.com</p> <p>16 For the Defendants, CVS Pharmacy Inc. and Rite Aid:</p> <p>17 BARNES & THORNBURG</p> <p>18 BY: KARA KAPKE, ESQ.</p> <p>19 11 S. Meridian Street</p> <p>20 317.231.6491</p> <p>21 kkapke@btlaw.com</p> <p>22 For the Defendant, Humana:</p> <p>23 FALKENBERG IVES LLP</p> <p>24 BY: MEGAN A. ZMICK, ESQ.</p> <p>25 230 West Monroe - Suite 2220</p> <p>Chicago, IL 60606</p> <p>312.566.4801</p> <p>maz@falkenbergives.com</p>
<p style="text-align: right;">Page 3</p> <p>1 A P P E A R A N C E S (Continued):</p> <p>2 For the Defendants, Mylan Pharmaceuticals Inc.,</p> <p>3 Mylan Laboratories Ltd., Mylan Inc., and Mylan N.V.:</p> <p>4 PIETRAGALLO GORDON ALFANO</p> <p>5 BOSICK & RASPANTI, LLP</p> <p>6 BY: CLEM TRISCHLER, ESQ.</p> <p>7 FRANK STOEY, ESQ.</p> <p>8 JASON M. REEFER, ESQ.</p> <p>9 One Oxford Centre</p> <p>10 301 Grant Street - 38th Floor</p> <p>11 Pittsburgh, PA 15219</p> <p>12 412.263.4385</p> <p>13 cct@pietragallo.com</p> <p>14 fhs@pietragallo.com</p> <p>15 jmr@pietragallo.com</p> <p>16 For the Defendants, Aurobindo Pharma USA, Inc.,</p> <p>17 Aurobindo Pharma Ltd., and Aurolife Pharma LLC:</p> <p>18 MORGAN LEWIS & BOCKIUS LLP</p> <p>19 BY: JOHN GISLESON, ESQ.</p> <p>20 STEVEN HUNCHUCK, ESQ.</p> <p>21 One Oxford Centre - 32nd Floor</p> <p>22 Pittsburgh, PA 15219</p> <p>23 412.560.7466</p> <p>24 john.gisleson@morganlewis.com</p> <p>25 steven.hunchuck@morganlewis.com</p> <p>For the Defendants, Zhejiang Huahai Pharmaceutical</p> <p>Co., Ltd., Solco Healthcare U.S., LLC, and Princeton</p> <p>Pharmaceutical Inc.:</p> <p>DUANE MORRIS LLP</p> <p>BY: ALYSON WALKER LOTMAN, ESQ.</p> <p>COLEEN HILL, ESQ.</p> <p>30 S. 17th Street</p> <p>Philadelphia PA 19103</p> <p>215.979.1177</p> <p>alotman@duanemorris.com</p> <p>cwhill@duanemorris.com</p>	<p style="text-align: right;">Page 5</p> <p>1 A P P E A R A N C E S (Continued)</p> <p>2 For the Defendants, Teva Pharmaceuticals USA, Inc.,</p> <p>3 Teva Pharmaceutical Industries Ltd., Actavis LLC,</p> <p>4 and Actavis Pharma, Inc.:</p> <p>5 GREENBERG TRAUIG, LLP</p> <p>6 BY: STEVEN M. HARKINS, ESQ.</p> <p>7 VICTORIA LOCKARD, ESQ.</p> <p>8 BRIAN RUBENSTEIN, ESQ.</p> <p>9 Terminus 200</p> <p>10 3333 Piedmont Road NE - Suite 2500</p> <p>11 Atlanta, GA 30305</p> <p>12 678.533.2312</p> <p>13 harkins@gtlaw.com</p> <p>14 lockardv@gtlaw.com</p> <p>15 rubensteinb@gtlaw.com</p> <p>16 MARTIN, HARDING & MAZZOTTI</p> <p>17 BY: ROSEMARIE RIDDELL BOGDAN, ESQ.</p> <p>18 100 Park Avenue Center - 16th Floor</p> <p>19 New York, NY 10017</p> <p>20 518.724.2207</p> <p>21 rosemarie.bogdan@1800law1010.com</p> <p>22 WALSH PIZZI O'REILLY FALANGA LLP</p> <p>23 BY: CHRISTINE GANNON, ESQ.</p> <p>24 Three Gateway Center</p> <p>25 100 Mulberry Street - 15th Floor</p> <p>Newark, NJ 07102</p> <p>973.757.1017</p> <p>cgannon@walsh.law</p> <p>For the Defendant, Albertson's LLC:</p> <p>BUCHANAN, INGERSOLL & ROONEY P.C.</p> <p>BY: CHRISTOPHER B. HENRY, ESQ.</p> <p>Carillon Tower</p> <p>227 W. Trade Street - Suite 600</p> <p>Charlotte, NC 28202</p> <p>704.444.3475</p> <p>christopher.henry@bipc.com</p>

<div>Page 6</div> <div>1 A P P E A R A N C E S (Continued):</div> <div>2 For the Defendant, McKesson Products:</div> <div>3 NORTON ROSE FULBRIGHT U.S. LLP</div> <div>4 BY: ELLIE NORRIS, ESQ.</div> <div>5 2200 Ross Avenue - Suite 3600</div> <div>6 Dallas, TX 75201</div> <div>7 214.855.8135</div> <div>8 ellie.norris@nortonrosefulbright.com</div> <div>9</div> <div>10</div> <div>11</div> <div>12</div> <div>13</div> <div>14</div> <div>15</div> <div>16</div> <div>17</div> <div>18</div> <div>19</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> <div>25</div> <div>8 ALSO PRESENT: WILLIAM MILLER, Videographer</div> <div>Veritext Legal Solutions</div>	<div>Page 8</div> <div>1 PREMARKED EXHIBITS</div> <div>2</div> <div>3 NUMBER DESCRIPTION PAGE</div> <div>4 Exhibit 1 R. Najafi Expert Declaration</div> <div>5 Exhibit 2 Emery Pharma Proposal</div> <div>6 Exhibit 3 Emery Invoice 8/2/2021</div> <div>7 Exhibit 4 Emery Invoice 1/28/2022</div> <div>8 Exhibit 5 Emery Invoice 1/31/2022</div> <div>9 Exhibit 6 Emery Invoice 2/1/2022</div> <div>10 Exhibit 7 Najafi C.V.</div> <div>11 Exhibit 8 Emery Article 4/6/2020</div> <div>12 Exhibit 13 Diovan Label</div> <div>13 Exhibit 17 Valsartan Label</div> <div>14 Exhibit 27 Article</div> <div>15 Exhibit 28 Valisure Letter 6/13/2019</div> <div>16 Exhibit 29 Information Sheet</div> <div>17 Exhibit 30 Valsartan specifications</div> <div>18 Exhibit 31 Article - Canada</div> <div>19 Exhibit 32 Nitrosamine Article</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> <div>25</div>
<div>Page 7</div> <div>1 INDEX TO WITNESSES</div> <div>2 WITNESS PAGE</div> <div>3 Ron Najafi, PhD</div> <div>4</div> <div>5 By Mr. Trischler:</div> <div>6 Direct Examination 10</div> <div>7 By Mr. Gisleson:</div> <div>8 Cross-examination 170</div> <div>9 By Mr. Harkins:</div> <div>10 Cross-examination 201</div> <div>11 By Mr. Nigh:</div> <div>12 Cross-examination 219</div> <div>13</div> <div>14</div> <div>15</div> <div>16</div> <div>17</div> <div>18</div> <div>19</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> <div>25</div>	<div>Page 9</div> <div>1 THE VIDEOGRAPHER: Good morning. We</div> <div>2 are going on the record at 9:09 a.m. Pacific time on</div> <div>3 February 3, 2022. This is Media Unit 1 of the video</div> <div>4 recorded deposition of Ron Najafi, PhD in regards to</div> <div>5 the valsartan/losartan litigation which is found in</div> <div>6 United States District Court, district of New</div> <div>7 Jersey, NDL No. 2875. My name is William Miller</div> <div>8 from the firm Veritext Legal Solutions and I am the</div> <div>9 videographer. The court reporter is Michelle</div> <div>10 Dawkins from the firm Veritext Legal Solutions. All</div> <div>11 counsel is noted on the stenographic record. Will</div> <div>12 the court reporter please swear in the witness.</div> <div>13 You're on mute, Michelle.</div> <div>14 THE COURT REPORTER: Sorry. Good</div> <div>15 morning. My name is Michelle Dawkins and I am the</div> <div>16 court reporter. The attorneys participating in this</div> <div>17 deposition acknowledge that I am not physically</div> <div>18 present in the deposition room and that I will be</div> <div>19 reporting this deposition remotely.</div> <div>20 They further acknowledge that in lieu</div> <div>21 of an oath administered in person, I will administer</div> <div>22 the oath remotely. The parties and their counsel</div> <div>23 consent to this arrangement and waive any objections</div> <div>24 to this manner of reporting.</div> <div>25 Please indicate your agreement by</div>

<p style="text-align: right;">Page 10</p> <p>1 stating your name and your agreement on the record.</p> <p>2 MR. TRISCHLER: Clem Trischler. So</p> <p>3 agreed on behalf of the defendants.</p> <p>4 MR. NIGH: Daniel Nigh, agreed on</p> <p>5 behalf of the plaintiffs.</p> <p>6 THE COURT REPORTER: Would the witness</p> <p>7 please state his full name.</p> <p>8 THE WITNESS: My name is Ron Najafi.</p> <p>9 THE COURT REPORTER: Mr. Najafi, would</p> <p>10 you please raise your right hand. Do you solemnly</p> <p>11 swear or affirm the testimony you will give at this</p> <p>12 deposition will be the truth, the whole truth and</p> <p>13 nothing but the truth?</p> <p>14 THE WITNESS: Yes, I do.</p> <p>15 THE COURT REPORTER: Thank you.</p> <p>16 DIRECT EXAMINATION</p> <p>17 BY MR. TRISCHLER:</p> <p>18 Q Sir, let me start by saying good</p> <p>19 morning. I think it's morning where you're located,</p> <p>20 so I'll say good morning to you.</p> <p>21 A Good morning to you.</p> <p>22 Q Thank you. My name is Clem Trischler.</p> <p>23 I am an attorney. I represent one of many</p> <p>24 defendants in litigation that's pending in the</p> <p>25 United States District Court for the district of New</p>	<p style="text-align: right;">Page 12</p> <p>1 true?</p> <p>2 MR. NIGH: Form objection. Outside</p> <p>3 the scope.</p> <p>4 A A drug, as I mentioned to you,</p> <p>5 Mr. Trischler, drug product contains impurities that</p> <p>6 could be harmless or could be hazardous.</p> <p>7 Q Is a drug product considered</p> <p>8 misbranded under federal law merely because it</p> <p>9 contains impurities?</p> <p>10 MR. NIGH: Form objection. Outside</p> <p>11 the scope.</p> <p>12 A A drug product, as I mentioned,</p> <p>13 contains impurities that could be harmless or could</p> <p>14 be hazardous and they could be misbranded because of</p> <p>15 the hazardous nature of the impurities.</p> <p>16 Q If a drug product contains impurities</p> <p>17 that are not harmful to public health, are those</p> <p>18 drug products considered to be misbranded?</p> <p>19 A No.</p> <p>20 MR. NIGH: Form objection. Outside</p> <p>21 the scope.</p> <p>22 Q If a drug substance -- every drug</p> <p>23 substance ever made in America has impurities,</p> <p>24 correct?</p> <p>25 A Every drug product that is made in</p>
<p style="text-align: right;">Page 11</p> <p>1 Jersey involving valsartan.</p> <p>2 I understand that you've been identified and</p> <p>3 designated an expert witness in this litigation; is</p> <p>4 that correct?</p> <p>5 A That's correct.</p> <p>6 Q I'd like to maybe start today by</p> <p>7 covering some basic concepts and see if we can get</p> <p>8 an agreement on a few basic points. Okay?</p> <p>9 A Okay.</p> <p>10 Q Number one, it is an established fact</p> <p>11 that all drug products contain impurities, agreed?</p> <p>12 A Yes, they do.</p> <p>13 Q A drug or a drug substance is not</p> <p>14 considered misbranded simply because it contains</p> <p>15 impurities, true?</p> <p>16 MR. NIGH: Form objection. Outside</p> <p>17 the scope.</p> <p>18 A A drug product contains impurities</p> <p>19 that are harmless and they could also contain</p> <p>20 impurities that could be extremely hazardous.</p> <p>21 Q That wasn't my question, sir. See if</p> <p>22 you can listen to my question and give me an answer</p> <p>23 to my question, please.</p> <p>24 A drug product is not considered misbranded</p> <p>25 simply because it contains impurities; isn't that</p>	<p style="text-align: right;">Page 13</p> <p>1 America or anywhere on the planet could contain</p> <p>2 impurities that are harmless or could be hazardous.</p> <p>3 Q I didn't ask you that question, sir.</p> <p>4 I said, isn't it a fact that every drug product ever</p> <p>5 made in America or on the planet does contain some</p> <p>6 impurities?</p> <p>7 MR. NIGH: He answered the question.</p> <p>8 He answered the question previously and it's outside</p> <p>9 the scope.</p> <p>10 MR. TRISCHLER: It's not an</p> <p>11 appropriate objection. It's not an appropriate</p> <p>12 instruction, if that's what it was. My question</p> <p>13 stands -- excuse me. And I'd like an answer.</p> <p>14 MR. NIGH: Objection. Asked and</p> <p>15 answered.</p> <p>16 MR. TRISCHLER: I don't know how you</p> <p>17 know that, since I haven't asked it yet, but let me</p> <p>18 try again.</p> <p>19 Q Every drug product ever made in the</p> <p>20 United States made for sale in the United States of</p> <p>21 America contains some impurities. Can we agree on</p> <p>22 that?</p> <p>23 MR. NIGH: Objection. Asked and</p> <p>24 answered.</p> <p>25 A I already responded to that question,</p>

<p style="text-align: right;">Page 14</p> <p>1 sir.</p> <p>2 Q I'm asking it again, then, sir. I ask</p> <p>3 you to answer my question, sir.</p> <p>4 A Sir, I will give you the same answer.</p> <p>5 Q What is the answer to my question?</p> <p>6 A I just gave you the answer to your</p> <p>7 question. Every drug product or every drug</p> <p>8 substance that's produced on the planet contains</p> <p>9 harmless and harmful impurities.</p> <p>10 Q If the mere presence of an impurity</p> <p>11 rendered a drug product adulterated and misbranded,</p> <p>12 then virtually pharmaceutical produced today would</p> <p>13 be deemed misbranded and adulterated, do you agree?</p> <p>14 MR. NIGH: Form objection. Outside</p> <p>15 the scope.</p> <p>16 A I did not say that. I said --</p> <p>17 Q I didn't -- sir, let me stop you. I</p> <p>18 didn't ask you what you said. I asked you a</p> <p>19 question. Do you understand that this is a question</p> <p>20 and answer session and I am permitted to ask you</p> <p>21 questions and you're required to give me responsive</p> <p>22 answers to those questions; is that a concept you</p> <p>23 understand?</p> <p>24 MR. NIGH: Mr. Trischler, you just now</p> <p>25 interrupted the witness in the middle of his answer.</p>	<p style="text-align: right;">Page 16</p> <p>1 I think you should -- I think it's -- the answer is</p> <p>2 clear.</p> <p>3 Q Do you agree that the mere presence of</p> <p>4 an impurity does not render a drug adulterated or</p> <p>5 misbranded?</p> <p>6 MR. NIGH: Objection. Scope.</p> <p>7 A I responded to your question.</p> <p>8 Q Sir, I am entitled to an answer to the</p> <p>9 question. I don't know if there was an internet</p> <p>10 issue. If there is was an answer, I didn't hear it.</p> <p>11 A There is no internet issues.</p> <p>12 Q I said I didn't hear. If there was an</p> <p>13 answer, I did not hear it.</p> <p>14 MR. NIGH: Was there an answer to the</p> <p>15 last question, Michelle?</p> <p>16 A I already answered it.</p> <p>17 Q I'm not talking to you, sir.</p> <p>18 A Let's move on to the next question.</p> <p>19 (The previous testimony as requested</p> <p>20 was read by the reporter.)</p> <p>21 MR. TRISCHLER: Okay. Thank you.</p> <p>22 Q It's not clear to me, so I would like</p> <p>23 an answer, please. Is it your testimony that the</p> <p>24 mere presence of an impurity renders a drug</p> <p>25 misbranded or adulterated; yes or no?</p>
<p style="text-align: right;">Page 15</p> <p>1 It wasn't completed.</p> <p>2 Q Do you understand that I am entitled</p> <p>3 to answers to my questions, sir?</p> <p>4 MR. NIGH: Do you understand not to</p> <p>5 interrupt the witness when he's answering your</p> <p>6 question?</p> <p>7 MR. TRISCHLER: I'm not going to get</p> <p>8 into a colloquy with you. I'm talking to the</p> <p>9 witness. Do you understand --</p> <p>10 MR. NIGH: Well, please don't</p> <p>11 interrupt the witness in the middle of his</p> <p>12 question -- I mean, in the middle of his answer.</p> <p>13 Q Do you understand that I'm entitled to</p> <p>14 responsive answers to my question, sir?</p> <p>15 A Clem, every drug product or drug</p> <p>16 substance that's produced on the planet contains</p> <p>17 harmless or harmful impurities. They could be</p> <p>18 misbranded if it contains extremely harmful</p> <p>19 impurities and they could not be misbranded if they</p> <p>20 are not harmful.</p> <p>21 Q So then you would agree with me that</p> <p>22 the mere presence of some impurity does not render a</p> <p>23 drug product misbranded or adulterated, right?</p> <p>24 MR. NIGH: Scope.</p> <p>25 A I already responded to your question.</p>	<p style="text-align: right;">Page 17</p> <p>1 MR. NIGH: Again, it's outside the</p> <p>2 scope.</p> <p>3 A I already responded to your question.</p> <p>4 Just look at the record. Go back to the records and</p> <p>5 you'll see my answer.</p> <p>6 Q So are you refusing to answer my</p> <p>7 question, sir?</p> <p>8 A I already responded to your question.</p> <p>9 Q No, you didn't. No you didn't. I</p> <p>10 asked a different question, sir. This is going to</p> <p>11 be a long day or else we're going to come back and</p> <p>12 I'm going to get fees, because Magistrate Judge</p> <p>13 Menaski has talked about obstructionist witnesses</p> <p>14 like this. So if you don't want to answer the</p> <p>15 question, that's fine. We'll halt the deposition,</p> <p>16 I'll get fees for it, and we'll come back here</p> <p>17 again.</p> <p>18 The question is pretty simple. Is it your</p> <p>19 position that the mere presence of an impurity</p> <p>20 renders a drug adulterated or misbranded; yes or no?</p> <p>21 MR. NIGH: Object to the colloquy</p> <p>22 given to the witness. Disagree, but I will ask the</p> <p>23 witness to answer this question again.</p> <p>24 A Again, this is not a "yes" or "no"</p> <p>25 answer, because mere presence of an impurity, if</p>

<p style="text-align: right;">Page 18</p> <p>1 it's safe impurity if it's determined safe, then 2 it's not misbranded, but if it's an unsafe impurity 3 then, yes, it is misbranded. 4 Q Does FDA require the supplier of an 5 active pharmaceutical ingredient used in generic 6 drug to use the same synthetic process used by the 7 RLB holder? 8 MR. NIGH: Form objection. 9 A The FDA does not require the generic 10 manufacturers to use exact procedure of the branded 11 drug. 12 Q When you say "exact procedure," my 13 question as are they required to use the same 14 synthetic process for developing and producing API. 15 The answer is no, correct? 16 MR. NIGH: Form objection. Outside 17 the scope. 18 A Mr. Trischler, am I pronouncing your 19 name right? 20 Q Close enough, sir. 21 A Mr. Trischler, FDA does not require a 22 generic manufacturer to use exact chemical procedure 23 as the brand to synthesize the generic drug. 24 Q And because the synthetic process used 25 by an RLD holder in a generic manufacturer may be</p>	<p style="text-align: right;">Page 20</p> <p>1 Q Yes. A generic drug manufacturer can 2 establish and satisfy FDA requirements for bio 3 equivalents even where the impurity profiles between 4 the RLD and generic equivalent product are 5 different. 6 A The generic drugs have to establish 7 bio equivalence when they make a generic drug. 8 Q Right. And you can -- 9 A A bio equivalence does not refer to, 10 you know, impurity profile. 11 Q I understand. My question was bio 12 equivalence can be established in having impurity 13 profiles that match as between the reference listed 14 drug and the generic applicant, correct? 15 A No, I didn't say that. 16 Q Then answer the question. 17 A Repeat your question please. 18 Q Sure. I said that a generic drug 19 manufacturer can meet FDA requirements for bio 20 equivalence without having an impurity profile that 21 matches the impurity profile of the reference listed 22 drug. 23 A The generic manufacturer can establish 24 bio equivalence or a synthetic process irrespective 25 of whether they have -- what kind of impurities they</p>
<p style="text-align: right;">Page 19</p> <p>1 different, it's not uncommon or unexpected that the 2 API used in an ANDA will have a different impurity 3 profile than the reference listed drug, is it? 4 MR. NIGH: Form objection. Outside 5 the scope. 6 A It is entirely possible that the 7 impurity profile of the generic drug may be 8 different. 9 Q In fact, there's absolutely no 10 requirement anywhere in the FDA regulations that 11 mandate that an RLD match or mirror the impurity 12 profile of the generic alternative, is there? 13 A The FDA does not require that the 14 generic drug manufacturer to match every impurity of 15 the branded drug. 16 However, they do require that the impurity is 17 to be determined safe. They do require that a 18 generic drug does sufficient due diligence to 19 determine the synthetic path is safe. 20 Q A generic manufacturer can establish 21 and satisfy FDA requirements for bio equivalents 22 even where the impurity profiles between the RLD and 23 the generic equivalent product are different, 24 correct? 25 A Could you repeat your question.</p>	<p style="text-align: right;">Page 21</p> <p>1 have. They could have harmful impurities, they 2 could have harmless impurities, and they can still 3 establish bio equivalence, but that's irrespective 4 of what kind of impurities they have. 5 Q Does the Food, Drug, and Cosmetic Act 6 contain a definition of an adulterated product? 7 MR. NIGH: Form. Outside the scope. 8 A To me, adulterated products are 9 products that have been contaminated. 10 Q Well, I appreciate your definition, 11 but I'm really not interested in it. My question 12 was, does the Food, Drug, and Cosmetic Act contain a 13 definition of what constitutes adulterated product? 14 A Yes, they do. 15 MR. NIGH: Hold on. Hold on. Object 16 to the colloquy. It's inappropriate. You can 17 answer. 18 A Adulterated products are products that 19 are mislabeled. They don't have proper label and 20 they could have toxic impurity in it, either 21 intentionally or inadvertently, and they could be 22 called adulterated. 23 Q Have you ever read the definition of 24 an adulterated drug product under the Food, Drug, 25 and Cosmetic Act?</p>

Page 22	Page 24
<p>1 A Yes, I have.</p> <p>2 Q Are you familiar with the definition</p> <p>3 under Section 351 of the Food, Drug, and Cosmetic</p> <p>4 Act?</p> <p>5 A I haven't looked at it exactly today,</p> <p>6 but I am familiar with that.</p> <p>7 Q Section 351 defined an adulterated</p> <p>8 drug as one where its strength differs from or its</p> <p>9 quality impurity fall below the standards set forth</p> <p>10 in the compendium.</p> <p>11 A I agree with that.</p> <p>12 MR. NIGH: Hold on. Was there a</p> <p>13 question?</p> <p>14 MR. TRISCHLER: There was.</p> <p>15 A You just read the definition.</p> <p>16 Q Right. And you would agree with that</p> <p>17 definition, right?</p> <p>18 MR. NIGH: Form objection. Outside</p> <p>19 the scope.</p> <p>20 Q You agree with that definition, sir?</p> <p>21 A If you're reading it from the regs,</p> <p>22 yes.</p> <p>23 Q And where there is a USP monograph,</p> <p>24 any article marketed in the United States must meet</p> <p>25 the requirements and specifications of the</p>	<p>1 Q Can you cite me an authority for the</p> <p>2 proposition that you just stated, that the USP</p> <p>3 monograph is a minimum standard? Where is that</p> <p>4 specified anywhere in the public literature?</p> <p>5 A I can't put my fingers on it right</p> <p>6 now, but I can look it up for you and show you.</p> <p>7 Q Well, we'll take multiple breaks</p> <p>8 during this day and so I'd like you to find me --</p> <p>9 A I will.</p> <p>10 Q Let me finish, please. Can I finish,</p> <p>11 please?</p> <p>12 A Absolutely.</p> <p>13 Q Sir, this is really difficult if we</p> <p>14 talk over one another. I'll do my best not to talk</p> <p>15 over you, but please let me finish my statement and</p> <p>16 my question.</p> <p>17 I'd like you to cite for me the authority for</p> <p>18 that novel proposition that you just offered, because</p> <p>19 I've not seen it.</p> <p>20 A I will.</p> <p>21 MR. NIGH: Hold on. Hold on. Hold</p> <p>22 on. Form objection and now I would object to</p> <p>23 whatever exercise there is that is supposed to do</p> <p>24 something during the breaks while he's trying to</p> <p>25 take restroom breaks. We are going far outside the</p>
Page 23	Page 25
<p>1 monograph. Agreed?</p> <p>2 A Would you repeat your question?</p> <p>3 Q Sure. Where there is a USP monograph,</p> <p>4 any drug product marketed in the United States must</p> <p>5 meet the requirements and specifications of that</p> <p>6 monograph?</p> <p>7 A USP drug is the minimum requirement</p> <p>8 that is required, absolute minimum. Manufacturers</p> <p>9 are required to go above and beyond those</p> <p>10 requirements.</p> <p>11 Q Are they required to meet -- where a</p> <p>12 monograph exists and applies, are manufacturers</p> <p>13 required to meet their specifications of the</p> <p>14 monograph?</p> <p>15 A You spoke too fast. You got cut out.</p> <p>16 Could you repeat?</p> <p>17 Q I'll try. Where there is a USP</p> <p>18 monograph that applies to a drug product are</p> <p>19 manufacturers required to meet those specifications</p> <p>20 and criteria in the monograph?</p> <p>21 MR. NIGH: Objection. Asked and</p> <p>22 answered.</p> <p>23 A I answered that question already. USP</p> <p>24 monograph is the minimum standards and manufacturers</p> <p>25 are required to go above and beyond that.</p>	<p>1 scope of his opinion and he has authority in his</p> <p>2 expert report if you want to read his certification.</p> <p>3 A Sir, can I respond to that question?</p> <p>4 I think that I can refer you to USP's website and</p> <p>5 under, basically, overview, USP monograph basically</p> <p>6 articulates that there is a minimum quality</p> <p>7 standards and the companies have to go above and</p> <p>8 beyond that.</p> <p>9 Q So I will find that on USP website?</p> <p>10 A You should able to find that on USP</p> <p>11 website, usp.com. Go to about USP and you should be</p> <p>12 able to find that.</p> <p>13 Q Will I find that requirement posted</p> <p>14 anywhere else?</p> <p>15 A I don't know. I'm sure there are. If</p> <p>16 you Google it, you will find it.</p> <p>17 Q Is there any requirement anywhere in</p> <p>18 the USP mandating that a generic equivalent product</p> <p>19 match or mirror the impurity profile of the RLD?</p> <p>20 MR. NIGH: Form objection.</p> <p>21 A There is the regs -- first of all, USP</p> <p>22 is not a regulatory body. USP is an independent</p> <p>23 company. The regs are clear. There is the concept</p> <p>24 of sameness, chemical equivalents, active</p> <p>25 equivalents, impurity equivalents, and there is the</p>

<p style="text-align: right;">Page 26</p> <p>1 concept of bio equivalents, therapeutic equivalents. 2 I can't comment on a lot of those things because I 3 am not a physician, but those are all spelled out in 4 the regs and you can look that up. 5 Q Where is the requirement for what you 6 call chemical equivalent, where is that term used in 7 the Food, Drug, and Cosmetic Act or the regulations 8 of the FDA? 9 A It's cited in my report, sir. 10 Q No, it's not. You don't provide any 11 citation for what constitutes chemical equivalents 12 in your report. 13 MR. NIGH: Objection. Hold on. I 14 don't know if that was a question. 15 A I responded to your question. 16 Q Show me in your report -- 17 A Look at my report. 18 Q Show me in your report where there is 19 a regulatory definition of what you just called 20 chemical equivalence. You can look at your -- take 21 your time. Look at your report and show me where 22 there is a definition of chemical equivalence either 23 in Food, Drug, and Cosmetic Act or regulations in 24 the FDA or in any guidance in the FDA, for that 25 matter.</p>	<p style="text-align: right;">Page 28</p> <p>1 If they are modifying the chemical procedure, 2 in which case in the case of your clients they are 3 modifying their brand's chemical procedure, then they 4 should expect a different chemical impurities. And 5 because they are modifying those chemical procedures 6 and the reagents, then they have an obligation to 7 identify those impurities and determine that they are 8 not genotoxic. 9 It's a very long winded question to my, 10 basically, one paragraph. It's No. 18 in my expert 11 report. 12 MR. TRISCHLER: Object and move to 13 strike as nonresponsive. 14 Q Do you remember what they question 15 was? 16 MR. NIGH: Hold on. This has already 17 been discussed that it's inappropriate during the 18 deposition. It's already been ruled on to object as 19 nonresponsive. The colloquies that you're giving, 20 Mr. Trischler, have been ruled on previously as 21 inappropriate. 22 You've also threatened sanctions. 23 That's also been ruled on as being inappropriate. 24 These are all the things that the defendants argued 25 that Mr. Slater was doing that was inappropriate and</p>
<p style="text-align: right;">Page 27</p> <p>1 A Okay. Hang on one second. I've got 2 to get the report from my desk. 3 THE VIDEOGRAPHER: Would you like to 4 go off the video record or would you like to stay 5 on? 6 MR. TRISCHLER: I don't care. 7 A Okay. I'm back. Sorry. I put this 8 on my computer. Basically, the generic drug 9 manufacturers have an ongoing federal duty of 10 sameness in their product and their reference is 11 reference No. 2. What that refers to is that the 12 identity of the active ingredients need to be 13 exactly the same. The chemical synthesis of the 14 actual ingredients need to be the same. And also, 15 this refers to the impurities that are present need 16 to be impurities that are either established by the 17 brand, established by the USP or impurities that are 18 established by the generic manufacturers; and those 19 impurities, if the generic is using exactly the 20 brand chemical procedure, if they are using the same 21 recipe with the same, basically, various ingredients 22 that they're using; different intermediates, 23 different reagents, if they are using the same, then 24 they should expect to have the same chemical 25 impurities.</p>	<p style="text-align: right;">Page 29</p> <p>1 now you're doing it yourself after Judge Menaski 2 ruled that all these issues are inappropriate. 3 We've got to put some brakes on this. 4 MR. TRISCHLER: Are you done with your 5 speech, Daniel? I just asked him. 6 MR. NIGH: No, no, no, no. You can't 7 ask him -- 8 MR. TRISCHLER: All I am asking is if 9 he remember -- 10 MR. NIGH: You can't move to strike. 11 It's inappropriate, and the combativeness with this 12 witness is completely inappropriate. It's not just 13 the speech. We can have a conversation with the 14 judge if we need to. 15 MR. TRISCHLER: Are you done? 16 MR. NIGH: No, I'm not done. I don't 17 think you're recognizing it. You're doing so many 18 inappropriate things. We have to not do this. You 19 can't badger this witness. 20 MR. TRISCHLER: If you need to call 21 the judge, go ahead. I welcome it. 22 MR. NIGH: Okay. 23 MR. TRISCHLER: I welcome it. 24 MR. NIGH: Are you going to keep doing 25 the things you're doing?</p>

<p style="text-align: right;">Page 30</p> <p>1 MR. TRISCHLER: Because I would love</p> <p>2 the judge to read this transcript.</p> <p>3 MR. NIGH: Do you have every intention</p> <p>4 to keep threatening for sanctions? Do you have</p> <p>5 every intention to keep moving to strike as</p> <p>6 nonresponsive, because if you do, then we might as</p> <p>7 well call the judge now, because he's already ruled</p> <p>8 that that's inappropriate.</p> <p>9 MR. TRISCHLER: I have already</p> <p>10 intention of asking relevant questions and I'm</p> <p>11 hoping to get some responsive answers to those</p> <p>12 questions.</p> <p>13 MR. NIGH: Okay. Well, I hope that</p> <p>14 you stop moving to strike as nonresponsive and</p> <p>15 threatening sanctions.</p> <p>16 MR. TRISCHLER: If you want to call</p> <p>17 the judge, I'd welcome it, because I would love for</p> <p>18 him to have the opportunity to read this transcript.</p> <p>19 A Please repeat your question.</p> <p>20 Q You used the term "chemical</p> <p>21 equivalents" and suggested that generic</p> <p>22 manufacturers have an obligation to establish</p> <p>23 chemical equivalents and my question to you, sir,</p> <p>24 was where in the Food, Drug, and Cosmetic Act or the</p> <p>25 regulations of the FDA is the term "chemical</p>	<p style="text-align: right;">Page 32</p> <p>1 molecular weight, identical to every sense of</p> <p>2 chemical sense. They should have same strength,</p> <p>3 same quality, purity.</p> <p>4 Purity here refers to the chemical purity of</p> <p>5 the drug and the impurity profiles of those drugs;</p> <p>6 and both potency. And potency is really a function</p> <p>7 of, you know, excipients and what excipients it's in</p> <p>8 and whether it's going to be released properly.</p> <p>9 So you get into a -- you know, I could talk</p> <p>10 about this for a couple hours, but that's what that</p> <p>11 is. And I'm referencing No. 2, No. 3, No. 4, these</p> <p>12 are basically the regs that are there.</p> <p>13 And the regs, as you well know, are vague</p> <p>14 enough and that can be -- you know, they are really</p> <p>15 the minimum standards. You know there is a concept</p> <p>16 that they say CGMP. C talks about current good</p> <p>17 manufacturing practices and "current" means the</p> <p>18 highest technology, technologies, of today; and the</p> <p>19 generic are responsible to living up to that standard</p> <p>20 of the latest standards.</p> <p>21 I hope -- that was a long answer to your</p> <p>22 question. I hope that I answered it.</p> <p>23 Q It was long. It was not an answer to</p> <p>24 the question, but I'll ask it again.</p> <p>25 A Well, you know, that's my answer. If</p>
<p style="text-align: right;">Page 31</p> <p>1 equivalents" anywhere defined and where would that</p> <p>2 requirement be established? That was what led you</p> <p>3 to look at your report. That's the question that</p> <p>4 I'm looking for an answer to.</p> <p>5 A Okay. Let me go back to my report</p> <p>6 again, okay. So I'm going to read back from my</p> <p>7 report, okay. Generic drug manufacturers have an</p> <p>8 ongoing federal duty of sameness in their product,</p> <p>9 reference No. 2. The generic manufacturers must</p> <p>10 demonstrate that their active ingredients are -- and</p> <p>11 have identical strength quality, purity -- I</p> <p>12 underlined that purity -- and potency and were</p> <p>13 applicable other characteristics as the reference</p> <p>14 listed drug.</p> <p>15 (Clarification requested by the</p> <p>16 reporter.)</p> <p>17 A I will repeat. Generic drug</p> <p>18 manufacturers have an ongoing federal duty of</p> <p>19 sameness, meaning equivalence, in their products.</p> <p>20 The generic manufacturers must demonstrate that</p> <p>21 their active ingredients -- in this case active</p> <p>22 compounds, the compound that's responsible for its</p> <p>23 therapeutic potential -- are the same as reference</p> <p>24 listed drug. "Same" here, Mr. Trischler, means</p> <p>25 identical; identical chemical structure, identical</p>	<p style="text-align: right;">Page 33</p> <p>1 you want, I can repeat the same thing that I just</p> <p>2 gave you.</p> <p>3 Q If you could stop talking for a</p> <p>4 minute, I'll try to ask another question. What you</p> <p>5 read from was paragraph 18 of your report, correct?</p> <p>6 A Correct.</p> <p>7 Q In paragraph 18 the words "chemical</p> <p>8 equivalent" never appear, do they?</p> <p>9 A Chemical equivalents --</p> <p>10 Q Do the words chemical equivalent</p> <p>11 appear?</p> <p>12 MR. NIGH: No, no, no, no, no, no, no,</p> <p>13 no.</p> <p>14 Mr. Trischler, he was clearly not</p> <p>15 finished with his answer there. No, no, no. That</p> <p>16 is completely inappropriate. You can finish your</p> <p>17 answer, Dr. Najafi.</p> <p>18 MR. TRISCHLER: He has to answer it</p> <p>19 first and then he can --</p> <p>20 MR. NIGH: No, he does not. Let him</p> <p>21 answer the question. Let him answer the question.</p> <p>22 That's completely inappropriate.</p> <p>23 MR. TRISCHLER: Now you're saying he</p> <p>24 can't answer the question?</p> <p>25 MR. NIGH: You're interrupting the</p>

<p style="text-align: right;">Page 34</p> <p>1 witness over and over and over again. He was not 2 done and he was starting to answer your question. 3 He got two words out and you interrupted him; two 4 words out. The video record is very clear on this. 5 MR. TRISCHLER: You just said he 6 doesn't have to answer the question. That's what 7 you just said. 8 A No, I did not say he doesn't have to 9 answer the question. I said he doesn't have to 10 answer it in the way that you want him to answer it 11 at the very beginning of the answer. 12 MR. TRISCHLER: Let's try it again. 13 MR. NIGH: How about you ask the 14 question and don't interrupt him, please. 15 MR. TRISCHLER: Let's try again. 16 MR. NIGH: That's pretty 17 inappropriate. 18 BY MR. TRISCHLER: 19 Q Do the words "chemically equivalent" 20 appear anywhere in paragraph 18 of your report? 21 A The word "equivalence" doesn't need to 22 appear in No. 18. Sameness is chemical equivalence. 23 Q Is there a definition of chemical 24 equivalence in the Food, Drug, and Cosmetic Act? 25 A I don't know.</p>	<p style="text-align: right;">Page 36</p> <p>1 safe, can be harmful. 2 Q Sir, I didn't ask you any of that. 3 All I simply asked you is you used the term 4 "impurity equivalence" earlier in your testimony and 5 my question is the term impurity equivalence a 6 defined term under the Food, Drug, and Cosmetic Act? 7 A I have to -- you know, I can look that 8 up during the break and get back to you. 9 Q Do you know if the term impurity 10 equivalence is defined in the FDA regulations or FDA 11 guidance? 12 A Purity profile is the same. You know, 13 basically you have to have -- you know, I responded 14 to the question. You're either following the 15 brand's recipe and you get the same purity/impurity 16 profile and the same purity or you're not following 17 brand's procedure. 18 If you're not following brand's procedure 19 you're going to get a different impurity profile and 20 those impurity profiles could have genotoxic compound 21 in it and it could be non-genotoxic compound in it. 22 Q Not my question again, sir. My 23 question was simply do you know whether the term 24 that you used "impurity equivalence" is a term that 25 is defined in any FDA guidance document or FDA</p>
<p style="text-align: right;">Page 35</p> <p>1 Q Is there a definition of chemical 2 equivalence in the regulations established by the 3 FDA? 4 A I don't know. 5 Q Is there a -- you used the term 6 "impurity equivalence." Is there a definition of 7 impurity equivalence under the Food, Drug, and 8 Cosmetic Act? 9 A The definition I just read, it's 10 the -- regs are clear the active ingredients need to 11 be the same. They need to be identical. The 12 quality, purity; you know, the identity of the drug 13 needs to be identical; potency, those are what 14 chemical equivalence is referring to. Perhaps I'm 15 not giving you the answer you like to hear, but 16 that's the answer. 17 Q Is impurity equivalence a defined term 18 under the Food, Drug, and Cosmetic Act? 19 A I gave you my answer, you know. You 20 have to have -- you know, the purity profile need to 21 have -- you either are following the brand procedure 22 and recipe, then you're going to end up with the 23 same impurity profile. If you're not following the 24 brand's procedure, you're going to end up with 25 different impurity profile. Those impurities can be</p>	<p style="text-align: right;">Page 37</p> <p>1 regulations? 2 A It may -- 3 MR. NIGH: Hold on. Form objection. 4 Just give a little bit of time between his question 5 and your answer, because I may have an objection, 6 form objection. You can answer. 7 A It may or may not. 8 Q Does FDA ever establish a requirement 9 that a drug manufacturer identify all impurities in 10 its drug label? 11 A Would you repeat your question? 12 Q Is there any FDA requirement for a 13 drug manufacturer to identify all impurities in its 14 drug label? 15 A There is a requirement that the 16 manufacturers identify all impurities that are 17 greater than certain percentage, and also there is a 18 requirement that the manufacturers identify any 19 potential genotoxic impurities. And typically those 20 are considered impurities of concern because of 21 their genotoxicity and those impurities are 22 predetermined or pre -- sort of predicted by the 23 expert chemist at the manufacturers based on certain 24 ingredients and based on certain chemical structures 25 that may be used.</p>

<p style="text-align: right;">Page 38</p> <p>1 Q You know what I mean by labeling?</p> <p>2 A Please define it.</p> <p>3 Q Labeling is a defined term under the</p> <p>4 Food, Drug, and Cosmetic Act. Are you familiar with</p> <p>5 the FDA definition of the term?</p> <p>6 A Why don't you give me the FDA</p> <p>7 definition.</p> <p>8 Q I don't have it in front of me, but</p> <p>9 for purposes of today I'm talking about the full</p> <p>10 prescribing information provided to prescribers and</p> <p>11 patients when their drug is dispensed. Okay?</p> <p>12 A Right.</p> <p>13 Q Do manufacturers identify impurities</p> <p>14 in their FDA-approved labeling?</p> <p>15 A They do. Manufacturers do identify</p> <p>16 impurities --</p> <p>17 Q Okay.</p> <p>18 A -- in their drug.</p> <p>19 Q As part of your work in this case, did</p> <p>20 you review the Diovan labeling?</p> <p>21 A No, I haven't.</p> <p>22 Q Have you reviewed the Exforge</p> <p>23 labeling?</p> <p>24 A No, I haven't.</p> <p>25 Q I think I sent some potential exhibits</p>	<p style="text-align: right;">Page 40</p> <p>1 your video feed.</p> <p>2 MR. NIGH: Is this document going to</p> <p>3 also be disclosed, because he can look at the full</p> <p>4 label and I don't see it here yet in the share file.</p> <p>5 MR. TRISCHLER: Frank -- hold on a</p> <p>6 second. I'm talking to Frank Stoy from my office</p> <p>7 who I also think is listening in. Frank, why don't</p> <p>8 you put in the chat all the things that we</p> <p>9 premarked.</p> <p>10 A I can't see this. I need to print</p> <p>11 this. So if you could email it to me, Daniel or</p> <p>12 Rosemarie, that would be great. I can print it so I</p> <p>13 can look at it. I can't read it.</p> <p>14 MR. STOY: I could try to draw up</p> <p>15 these documents in the chat as we use it. There is</p> <p>16 also a share file link that I think Layne just put</p> <p>17 in the chat where, Dr. Najafi, you should be able to</p> <p>18 download the exhibits as they're marked.</p> <p>19 THE WITNESS: Great.</p> <p>20 BY MR. TRISCHLER:</p> <p>21 Q So you can't see this, is that what</p> <p>22 you're telling me?</p> <p>23 A I can't see it, no. I have a -- it's</p> <p>24 very small on my screen.</p> <p>25 Q Well, then I guess --</p>
<p style="text-align: right;">Page 39</p> <p>1 ahead of time to the court reporter that we</p> <p>2 premarked. I think I premarked Exhibit 13 as a</p> <p>3 Diovan label.</p> <p>4 A I was told -- I got a piece of mail</p> <p>5 here. I was told not to open it until you guys</p> <p>6 instruct me. Is that the one you want me to open</p> <p>7 it?</p> <p>8 Q No, I didn't ask you to open anything.</p> <p>9 A Okay. You want me to open it?</p> <p>10 Q No. I have no idea what you're</p> <p>11 talking about. I didn't ask you to do anything.</p> <p>12 MS. HILTON: Just for the record,</p> <p>13 Clem, this was something that John Giselson and the</p> <p>14 Aurobindo counsel had sent to Dr. Najafi and</p> <p>15 instructed him not to open it. So Dr. Najafi, I</p> <p>16 think, continue to keep that box unopened until</p> <p>17 Mr. Giselson and the lawyers for Aurobindo question</p> <p>18 you.</p> <p>19 BY MR. TRISCHLER:</p> <p>20 Q What we marked as Exhibit 13 is a copy</p> <p>21 of the FDA approved labeling for Diovan.</p> <p>22 A Okay.</p> <p>23 Q Have you ever seen this before, sir?</p> <p>24 A Could you make it bigger?</p> <p>25 THE VIDEOGRAPHER: Sir, we just lost</p>	<p style="text-align: right;">Page 41</p> <p>1 A What are you referring to?</p> <p>2 Q Well, I guess -- hold on. I guess we</p> <p>3 need to take a break until you can see it.</p> <p>4 THE VIDEOGRAPHER: Going off the</p> <p>5 record, yes?</p> <p>6 MR. TRISCHLER: Yes.</p> <p>7 THE VIDEOGRAPHER: The time is 9:58.</p> <p>8 This concludes Media 1.</p> <p>9 (A recess was taken.)</p> <p>10 (After the recess the following</p> <p>11 occurred:)</p> <p>12 THE VIDEOGRAPHER: The time is now</p> <p>13 10:14. We are back on the video record. This</p> <p>14 begins Media 2. And counsel, would you like me to</p> <p>15 put the document that was on the screen up again?</p> <p>16 MR. TRISCHLER: Yes, please.</p> <p>17 BY MR. TRISCHLER:</p> <p>18 Q Doctor, earlier we had talked about</p> <p>19 the definition of "adulterated" under the Food, Drug</p> <p>20 and Cosmetic Act. Would you agree with me that the</p> <p>21 term "misbranded" is also defined under the statute?</p> <p>22 MR. NIGH: Objection. Scope.</p> <p>23 A Would you repeat your question?</p> <p>24 Q Is the term "misbranded" defined in</p> <p>25 the Food, Drug, and Cosmetic Act?</p>

<p style="text-align: right;">Page 42</p> <p>1 MR. NIGH: Objection to form.</p> <p>2 A Yes, I believe it is defined.</p> <p>3 Q And under the Food, Drug, and Cosmetic</p> <p>4 Act a drug is deemed misbranded when its labeling</p> <p>5 proves to be false or misleading. Can we agree on</p> <p>6 that definition?</p> <p>7 MR. NIGH: Objection. Scope.</p> <p>8 A I agree that a misbranded drug</p> <p>9 contains something that shouldn't be there.</p> <p>10 Q Is that your definition or are you</p> <p>11 suggesting that's the definition provided in the</p> <p>12 Food, Drug, and Cosmetic Act?</p> <p>13 MR. NIGH: Objection. Form.</p> <p>14 A A misbranded drug is a drug that has</p> <p>15 false or misleading label.</p> <p>16 Q Okay. Thank you. So now we are</p> <p>17 looking at the labeling for Diovan. I have marked</p> <p>18 it as Exhibit 13. Are you now able to see it?</p> <p>19 A Yes. I have it on my second monitor</p> <p>20 here so I can actually see it. I am going to be</p> <p>21 looking at my own version, but I have it. I am</p> <p>22 looking at the same area.</p> <p>23 Q All right. And can you go through</p> <p>24 this -- the label that we marked as Exhibit No. 13</p> <p>25 and tell me where Novartis discloses the impurities</p>	<p style="text-align: right;">Page 44</p> <p>1 They need to disclose it on their batch record.</p> <p>2 They need to identify it, all their degradation</p> <p>3 products, and disclose it to the FDA in their</p> <p>4 filing.</p> <p>5 Q In their -- sorry. I thought you were</p> <p>6 finished. Well, that's true in part, but isn't it</p> <p>7 also true that all -- that there is an allowance for</p> <p>8 unknown and unidentified impurities in every drug</p> <p>9 product made and sold in America?</p> <p>10 MR. NIGH: Was that a question?</p> <p>11 MR. TRISCHLER: Yes, sir.</p> <p>12 MR. NIGH: Objection. Scope.</p> <p>13 A What was your question?</p> <p>14 Q I said isn't it true that there is an</p> <p>15 allowance for unknown impurities in every drug</p> <p>16 product?</p> <p>17 MR. NIGH: Objection. Scope.</p> <p>18 A There is an allowance for unknown</p> <p>19 impurities for every drug, provided they are not</p> <p>20 genotoxic.</p> <p>21 Q And prior to June of 2018, can we</p> <p>22 agree that there was no requirement established by</p> <p>23 the FDA or specified in USP for nitrosamine-specific</p> <p>24 testing?</p> <p>25 MR. NIGH: Objection. Scope.</p>
<p style="text-align: right;">Page 43</p> <p>1 in its Diovan product?</p> <p>2 A Okay. Let me look.</p> <p>3 MR. NIGH: Objection. Scope.</p> <p>4 A So Novartis does not mention this</p> <p>5 particular genotoxic impurities, because their</p> <p>6 product didn't have any.</p> <p>7 Q That wasn't my question. My question</p> <p>8 was where do they list any impurities.</p> <p>9 MR. NIGH: Form objection. Scope.</p> <p>10 A This is not the place where they would</p> <p>11 list their impurities.</p> <p>12 Q Is there any requirement that</p> <p>13 impurities -- that a drug manufacturer list</p> <p>14 impurities in its label, FDA labeling?</p> <p>15 MR. NIGH: Objection. Scope.</p> <p>16 A I don't think there is any</p> <p>17 requirement, per se, to list it. You know, if</p> <p>18 you're looking at this label, you know, the only</p> <p>19 thing you see is the active compound.</p> <p>20 Q And that's my question, sir. Does any</p> <p>21 drug manufacturer list or identify impurities in its</p> <p>22 labeling?</p> <p>23 MR. NIGH: Objection. Scope.</p> <p>24 A I don't believe they do, but they need</p> <p>25 to file it with the FDA. They need to let FDA know</p>	<p style="text-align: right;">Page 45</p> <p>1 Q Are you referring to particular</p> <p>2 valsartan drug?</p> <p>3 A No, I'm talking about any drug. I</p> <p>4 said prior to June of 20-- 18, are you aware of any</p> <p>5 requirement that was established by the FDA or</p> <p>6 specified in USP that required nitrosamine-specific</p> <p>7 impurity testing.</p> <p>8 MR. NIGH: Objection. Scope.</p> <p>9 A So my answer is genotoxic compounds</p> <p>10 need to be identified per the ICH guideline M7, and</p> <p>11 I refer you to that. They need to be identified and</p> <p>12 they need to be reported and they need to be</p> <p>13 controlled and managed and, you know, the whole</p> <p>14 nine yards. And yes, they would have to be -- they</p> <p>15 would have to be measured and by various</p> <p>16 instrumentation: GC, GCMS, LCMS, they need to know</p> <p>17 the amount; and there was a limit on the amount</p> <p>18 allowable for various impurities genotoxic</p> <p>19 impurities, I should say.</p> <p>20 UNIDENTIFIED SPEAKER: Excuse me,</p> <p>21 counsel. Are you in need of another court reporter</p> <p>22 or are you all set, Michelle? I was just told to</p> <p>23 join the meeting.</p> <p>24 (Off the record.)</p> <p>25 Q Do you know what the acceptance</p>

<p style="text-align: right;">Page 46</p> <p>1 criteria was for impurities under the valsartan USP</p> <p>2 monograph in the summer of 2018?</p> <p>3 MR. NIGH: Objection. Form.</p> <p>4 Q The acceptance criteria was to produce</p> <p>5 the active compound and have impurities that are</p> <p>6 safe, that are inert and have a safe drug. That was</p> <p>7 the requirement, and there were impurities that were</p> <p>8 listed that could potentially be formed and those</p> <p>9 impurities are typically impurities that the brand</p> <p>10 discloses to the USP or USP also, you know, acquires</p> <p>11 it through their own research.</p> <p>12 MR. TRISCHLER: Can you put up what</p> <p>13 was premarked as Exhibit 17, please.</p> <p>14 A Okay.</p> <p>15 Q Have you seen this document before,</p> <p>16 sir?</p> <p>17 A Hang on a second. Let me -- this is</p> <p>18 you is -- yes I have.</p> <p>19 Q What is it?</p> <p>20 A It's a USP, you know, monograph for</p> <p>21 the -- basically, limits of different impurities and</p> <p>22 different -- you know, the acceptance criteria from</p> <p>23 USP's point of view.</p> <p>24 Q And what's the acceptance criteria for</p> <p>25 impurities under the USP standards as set forth in</p>	<p style="text-align: right;">Page 48</p> <p>1 compound such as NDMA or NDEA, presupposes.</p> <p>2 Q Where does it say that in the USP</p> <p>3 monograph?</p> <p>4 A You don't see that on the screen. If</p> <p>5 it was part of the impurity profile, it would have</p> <p>6 been mentioned. Since it's not, it means it</p> <p>7 shouldn't have any.</p> <p>8 Q Today in 2021 what does the USP for</p> <p>9 valsartan provide as to the impurity acceptance</p> <p>10 criteria?</p> <p>11 MR. NIGH: Objection. Scope.</p> <p>12 A I haven't looked at the latest -- I</p> <p>13 don't have access to that document but, you know, it</p> <p>14 presupposes there is no genotoxic compound in</p> <p>15 valsartan.</p> <p>16 Q I'm puzzled by that, sir. Where is it</p> <p>17 written anywhere in regulations, guidance or USP</p> <p>18 acceptance criteria that these numbers presuppose no</p> <p>19 genotoxic impurities; does anyone say that other</p> <p>20 than Ron Najafi?</p> <p>21 MR. NIGH: Object to the colloquy and</p> <p>22 object to scope.</p> <p>23 MR. TRISCHLER: There was no colloquy.</p> <p>24 That was a question.</p> <p>25 MR. NIGH: No, but beginning part of</p>
<p style="text-align: right;">Page 47</p> <p>1 Exhibit 17?</p> <p>2 MR. NIGH: Objection. Scope.</p> <p>3 A The acceptance criteria is to have,</p> <p>4 you know, basically each total -- each individual</p> <p>5 impurities not basically greater than .2 percent or</p> <p>6 not important .2 or .4, various impurities that are</p> <p>7 listed, and that would be the accepted criteria.</p> <p>8 Q If you go to the next page of</p> <p>9 Exhibit 17, in particular Table 1, it lists the</p> <p>10 specification and acceptance criteria for unknown</p> <p>11 impurities is 0.1 percent, correct?</p> <p>12 MR. NIGH: Objection. Scope.</p> <p>13 A Let me. Are you -- okay. Thank you</p> <p>14 for making it bigger. So, yeah. As you can see</p> <p>15 from this impurity profile, there is no genotoxic</p> <p>16 impurity mentioned here.</p> <p>17 Q I didn't ask you that, sir. I said,</p> <p>18 what's the acceptance -- was the criteria in the USP</p> <p>19 monograph for unknown impurities 0.1 percent.</p> <p>20 That's the only question I asked.</p> <p>21 MR. NIGH: Form objection. His answer</p> <p>22 was responsive and I object to the colloquy. You</p> <p>23 could answer.</p> <p>24 A The acceptance criteria presupposes</p> <p>25 that the compound in question has no genotoxic</p>	<p style="text-align: right;">Page 49</p> <p>1 that question started out with, "I'm puzzled." That</p> <p>2 is a colloquy.</p> <p>3 Q So this -- I will ask it again, sir.</p> <p>4 This idea that these acceptance criteria presuppose</p> <p>5 that there is no genotoxic impurities, where is that</p> <p>6 coming from?</p> <p>7 MR. NIGH: Objection.</p> <p>8 Q Where --</p> <p>9 MR. NIGH: Form objection.</p> <p>10 Q Where is that?</p> <p>11 MR. NIGH: Sorry. Scope.</p> <p>12 A I refer you to USP website and</p> <p>13 specifically there is a specific mention that for</p> <p>14 impurities known that are suspected carcinogen that</p> <p>15 are toxic, that are genotoxic, a quantitation and</p> <p>16 detection limit shall be established. This is USP.</p> <p>17 It is ICH guideline, ICH M7. It's FDA. You know,</p> <p>18 if you want me, I can specifically cite you page and</p> <p>19 the language during the break.</p> <p>20 Q We don't have to. I would like that,</p> <p>21 but we don't have to do it right now, because during</p> <p>22 the last break I did some homework and I would ask</p> <p>23 you to take a look at Exhibit 27. This is the USP</p> <p>24 website you were telling me about, right?</p> <p>25 A Right.</p>

<p style="text-align: right;">Page 50</p> <p>1 MR. NIGH: Objection to the colloquy.</p> <p>2 Q And you said this is the site where I</p> <p>3 can go to where there is going to be a statement and</p> <p>4 public pronouncement that the USP specifications are</p> <p>5 minimum standards, so look at Exhibit 27 and tell me</p> <p>6 where it says that, sir.</p> <p>7 MR. NIGH: Form objection. Outside</p> <p>8 the scope. Mischaracterizes his testimony. You can</p> <p>9 answer.</p> <p>10 A I am not sure what you found on USP</p> <p>11 website, if you found the right page, but I will</p> <p>12 point that to you later.</p> <p>13 Q I'm asking you to take a look at</p> <p>14 Exhibit 27 and tell me if there is anything on</p> <p>15 Exhibit 27 that suggests that the USP monographs</p> <p>16 specifications are minimum standards.</p> <p>17 A So, specifically monograph articulates</p> <p>18 the quality expectation for medicines, including for</p> <p>19 its identity, strength and performance. They are</p> <p>20 also described a test to validate that in medicine</p> <p>21 that its ingredients meet these criteria and</p> <p>22 basically, I would have to do my own search to show</p> <p>23 you that specific language. I'm not sure if you</p> <p>24 have it in the documents you gave to me.</p> <p>25 Q Exhibit 27 is a multipage document.</p>	<p style="text-align: right;">Page 52</p> <p>1 occurred.)</p> <p>2 THE VIDEOGRAPHER: The time is 10:46.</p> <p>3 We are back on the video record. You may proceed.</p> <p>4 BY MR. TRISCHLER:</p> <p>5 Q Okay. We just took a break. Doctor,</p> <p>6 you said that you wanted to take some time to review</p> <p>7 some material. Have you had the chance to do that?</p> <p>8 A Okay.</p> <p>9 Q Have you had the chance to look at</p> <p>10 whatever it was?</p> <p>11 A Yes, I did. I did.</p> <p>12 Q Hold on. That's the only question I</p> <p>13 asked you right now. Did you talk to anyone while</p> <p>14 we were on that break?</p> <p>15 A No, I didn't.</p> <p>16 Q You reviewed while we were on that</p> <p>17 break?</p> <p>18 A Yes.</p> <p>19 MR. NIGH: It wasn't really a break</p> <p>20 for Dr. Najafi.</p> <p>21 Q What did we review at the time we went</p> <p>22 off the record at your request?</p> <p>23 A I looked at the USP website.</p> <p>24 Q Okay. And did you find anything on</p> <p>25 the USP website suggesting that the USP monographs</p>
<p style="text-align: right;">Page 51</p> <p>1 Do you want to look at the whole thing and see if</p> <p>2 there's anything in there to suggest that USP</p> <p>3 requirements are minimum standards?</p> <p>4 A If you give me a second, I will look</p> <p>5 it up for you.</p> <p>6 Q Sure. Let's go off the record.</p> <p>7 A Let's go off line.</p> <p>8 MR. NIGH: Hold on. What are you</p> <p>9 looking up at this point, Dr. Najafi, the exhibit?</p> <p>10 You're looking at the exhibit or you're looking it</p> <p>11 up online?</p> <p>12 THE WITNESS: No. I want to go online</p> <p>13 and look up something for him.</p> <p>14 THE VIDEOGRAPHER: Are we all okay to</p> <p>15 go off the record?</p> <p>16 MR. TRISCHLER: Yes.</p> <p>17 MR. NIGH: No. Do you want him to go</p> <p>18 online and look this up for you, Mr. Trischler?</p> <p>19 MR. TRISCHLER: The witness said he</p> <p>20 wants to, so let's go off the record and we will</p> <p>21 come back when he's ready.</p> <p>22 THE VIDEOGRAPHER: The time is 10:32.</p> <p>23 We are going off the video record.</p> <p>24 (A recess was taken.)</p> <p>25 (After the recess the following</p>	<p style="text-align: right;">Page 53</p> <p>1 were minimum standards?</p> <p>2 A So I looked at exact same page that</p> <p>3 you're looking at, which is USP.org. It's about USP</p> <p>4 public policy overview of monograph.</p> <p>5 Q Did you find anything on that website</p> <p>6 that we marked the pages of which we marked</p> <p>7 Exhibit 27 that indicate the USP monographs are</p> <p>8 minimum standards?</p> <p>9 MR. NIGH: Form objection. That</p> <p>10 document is just one small part of the entire</p> <p>11 USP.org. You can see the site map which has much</p> <p>12 more than this little snippet from the website.</p> <p>13 MR. TRISCHLER: Is that a proper</p> <p>14 objection?</p> <p>15 MR. NIGH: It actually is, because you</p> <p>16 misrepresented the document, so absolutely it is.</p> <p>17 MR. TRISCHLER: You know better.</p> <p>18 MR. NIGH: No. You misrepresented the</p> <p>19 document in your question just now.</p> <p>20 Q Sir, I'm just asking you to tell me</p> <p>21 where it is published that USP monographs are</p> <p>22 minimum standards. You made that representation.</p> <p>23 Where is it published?</p> <p>24 A Yes. So I would like to point you to</p> <p>25 No. 1 where it says (1) monograph in your exhibit.</p>

<p style="text-align: right;">Page 54</p> <p>1 Monograph articulates the quality expectations, 2 quality expectations to anybody familiar with the 3 art; art of synthesis and manufacturing. It means 4 minimum expectation. That's my understanding and 5 that's my pure understanding. 6 Those quality expectations, it's like, you 7 know, just like the bar that you have to have, you 8 know, and that's a starting point for a medicine 9 including for its identity, strength, purity, 10 performance. They also describe the tests to 11 validate and so forth and so on, which is all -- you 12 can read it as well. That's the minimum standard. 13 Q And so if we go back to the monograph 14 itself which we had previously marked, I think, as 15 Exhibit 17, you remember the table told us that 16 under that -- it is the next page. Thank you. 17 The table told us that the acceptance criteria 18 for unknown impurities was 0.1 percent, right? 19 A Right. 20 Q And 0.1 percent, that translates to 21 about 1,000 parts per million, right? 22 A Right. 23 Q And if we're talking about a 320 24 milligram tablet and we wanted to convert that to 25 nanograms, that would be about 320,000 nanograms,</p>	<p style="text-align: right;">Page 56</p> <p>1 nanograms. If they are genotoxic, no. 2 Q I am going to switch gears for a 3 minute. 4 A And you can refer you to my reference 5 on ICH guideline M7. 6 Q I didn't even ask you a question. 7 A It's part of the previous question. 8 Q You told me at the beginning of this 9 deposition that you'd been retained in the valsartan 10 MDL to offer expert testimony right? 11 A Yes. 12 Q Do you remember when you were first 13 retained in the valsartan matters? 14 A Repeat your question, please. 15 Q Do you remember when you were first 16 retained in the valsartan matters? 17 A I think I was retained sometime in 18 2019; October, maybe September, October 2019. 19 Q Can you identify the plaintiff's 20 lawyer or lawyers who retained you? 21 A Yes. 22 Q Can you identify them? 23 A They're on the phone. They're on the 24 Zoom. 25 Q Well, I'd like you to tell me their</p>
<p style="text-align: right;">Page 55</p> <p>1 right? 2 A Yes. 3 MR. NIGH: Objection. Scope. 4 Q So, according to USP, whether it's 5 standards or minimum, maximum or something in 6 between, it's acceptable to have a drug product with 7 unknown impurities of as high as 320 nanograms in a 8 320-milligram tablet, right? 9 MR. NIGH: Objection. Scope. 10 A USP also refers you to ICH guidelines 11 and genotoxic guidelines, and those genotoxic 12 compounds could be as low as, you know, zero. 13 Q But it could be as high as 320,000 14 nanograms? 15 A Could be as high as that level, but 16 the drug would not probably get approved. 17 Q Well, it would meet USP acceptance 18 criteria, right? 19 A No, it wouldn't. 20 Q An unknown impurity -- we just went 21 through the table. An unknown impurity in a 22 320-milligram drug product can be as high as 320,000 23 nanograms, right? 24 A Unknown impurities that are not 25 genotoxic can be as high as, you know, 300,000</p>	<p style="text-align: right;">Page 57</p> <p>1 names, please. 2 A Daniel, Rosemarie and Brad. 3 Q Daniel Nigh -- for the record, Daniel 4 Nigh, Rosemarie -- what is Rosemaries' last name? 5 A Bogdan. 6 Q And who is the third person you 7 mentioned? 8 A Brad Vaughn. 9 Q I'm sorry. Did you say Vaughn? 10 A Yes. It's the firm Pendley Bovin & 11 Hoffman, I think, or -- 12 Q All right. Have you also been 13 retained by plaintiff's counsel as a consultant in 14 the ranitidine MDL? 15 MR. NIGH: Hold on. I am going to 16 instruct him not to answer. 17 MR. TRISCHLER: Can I ask on what 18 basis? 19 MR. NIGH: Actually, we have disclosed 20 an opinion, so you can ask him. Go ahead. 21 Q Have you also been retained as a 22 plaintiff's consultant in the ranitidine MDL? 23 A I have been retained as a consultant 24 in the ranitidine matter. 25 Q And in this litigation, the valsartan</p>

<p style="text-align: right;">Page 58</p> <p>1 cases, do you understand that claims have been 2 brought against -- well, strike that. 3 Let me ask you this first: In the ranitidine 4 litigation, do you understand that claims have been 5 brought against brand and generic manufacturers based 6 on the presence of nitrosamines in 7 ranitidine-containing products? 8 A Could you repeat your question? 9 Q Sure. In connection with your work in 10 the ranitidine litigation, I'm simply asking you if 11 you have an understanding that in that lawsuit there 12 have been claims brought against both brand and 13 generic drug manufacturers based on the presence of 14 nitrosamines in drugs made by both brand 15 manufacturers and generic. 16 A I believe so. 17 Q Do you know how many drug 18 manufacturers and drug suppliers have been sued by 19 plaintiffs in the ranitidine MDL stating their 20 products contain nitrosamines? 21 A There are many, many. I can't tell 22 you. 23 Q Is the number more than 75? 24 A I don't think so. 25 Q More than 65?</p>	<p style="text-align: right;">Page 60</p> <p>1 disclosed in the metformin litigation. 2 Q Aside from the valsartan MDL and the 3 ranitidine MDL, are there any nitrosamine litigation 4 matters that you're working on where you have been 5 retained to offer expert testimony? 6 MR. NIGH: And I would instruct that 7 if you were working on any other matters where your 8 expert opinion hasn't been disclosed, that you not 9 answer that question, because it's privileged. 10 Q Can you answer that question, Doctor? 11 MR. NIGH: Can you ask the question, 12 any other litigations where his expert opinion has 13 been disclosed? 14 MR. TRISCHLER: I thought that was the 15 question I did ask. Do you want me to ask it again? 16 MR. NIGH: No, you actually didn't ask 17 that way, but if you ask that way, then we don't 18 have to worry about the privilege objection. 19 Q Other than ranitidine and valsartan, 20 have you been retained by plaintiffs in other 21 litigation where your opinions have been disclosed 22 to provide testimony on matters relating to 23 nitrosamines? 24 A So we are a contract lab and, you 25 know, less than 10 percent of our business comes</p>
<p style="text-align: right;">Page 59</p> <p>1 A I don't think so. 2 Q More than 50? 3 A I don't think so. 4 Q Can you give me an estimate of how 5 many drug manufacturers and drug suppliers you 6 understand to be part of that case? 7 A Probably a dozen. 8 Q Do you know how many drug 9 manufacturers and drug suppliers are part of this 10 case, the valsartan MDL? 11 A I don't, perhaps a dozen. 12 Q In addition to the ranitidine MDL and 13 this lawsuit, is it true you're also working for 14 plaintiffs' lawyers in the metformin MDL? 15 MR. NIGH: Form objection. I am going 16 to instruct him not to answer. 17 MR. TRISCHLER: What's the basis, 18 Daniel, just so I have it on the record? 19 MR. NIGH: If he is a consulting 20 witness, there is no opinion that's been disclosed 21 of metformin. 22 MR. TRISCHLER: Well, I don't know. 23 I'm asking. Are you suggesting he's not a disclosed 24 expert in that case? 25 MR. NIGH: There's been no experts</p>	<p style="text-align: right;">Page 61</p> <p>1 from litigation support but, yes, we have been 2 retained by other firms regarding nitrosamines. 3 Q And what other firms would that be? 4 MR. NIGH: Again, was there an opinion 5 disclosed in any other litigation other than 6 ranitidine and valsartan, any expert reports? 7 Otherwise, this is privileged material and I would 8 instruct you not to answer. 9 MR. TRISCHLER: I'm just trying to ask 10 a predicate question, whether there are any others. 11 MR. NIGH: He just said no. I don't 12 know if you heard him. 13 MR. TRISCHLER: I did not. 14 A I did not disclose any expert opinion 15 on any other matters. 16 Q Except ranitidine and valsartan, 17 that's your testimony? 18 A Valsartan we have not disclosed any 19 expert opinion either. We have not finalized our 20 expert opinion as of yet. 21 Q Well, that's news to me, because I 22 thought you did file a declaration that brings us 23 here today that contains some opinions and that's 24 what we're here to talk about. 25 In any event, I think what you're suggesting</p>

<p style="text-align: right;">Page 62</p> <p>1 to me is that you may have valsartan at a later date</p> <p>2 and you may have other reports and other opinions; is</p> <p>3 that what you're telling me?</p> <p>4 A That's correct.</p> <p>5 Q My only question -- only thing I am</p> <p>6 trying to get to the bottom of is whether there is</p> <p>7 any other litigation matters involving nitrosamines</p> <p>8 that you have been involved in where you've</p> <p>9 disclosed an expert opinion other than ranitidine</p> <p>10 and valsartan?</p> <p>11 A No.</p> <p>12 Q The company that you own and operate,</p> <p>13 as I understand it, is called Najafi Pharma Inc; is</p> <p>14 that right?</p> <p>15 A Najafi Pharma Inc.</p> <p>16 Q Najafi Pharma. Sorry about that.</p> <p>17 A Same as my last name.</p> <p>18 Q Yes, and Najafi Pharma does businesses</p> <p>19 as Emery Pharma?</p> <p>20 A Yes, that's correct.</p> <p>21 Q Is Najafi Pharma Inc. a corporation?</p> <p>22 A Yes, that's correct.</p> <p>23 Q Is it publicly or privately held?</p> <p>24 A It's a privately held corporation.</p> <p>25 Q Who are the shareholders of that</p>	<p style="text-align: right;">Page 64</p> <p>1 Q Can you tell us what total revenues</p> <p>2 have been generated by Emery Pharma by your work as</p> <p>3 a paid consultant for plaintiffs in nitrosamine</p> <p>4 litigation?</p> <p>5 A I don't have the exact number, but</p> <p>6 it's around 200.</p> <p>7 MR. NIGH: No, no, no. Sorry. Sorry.</p> <p>8 I would object. You can ask what percentage of his</p> <p>9 revenue over the last few years, but you can't ask</p> <p>10 total revenue numbers.</p> <p>11 Q Who would --</p> <p>12 MR. NIGH: If you want to ask for this</p> <p>13 litigation, that's fair, but you can't ask for all</p> <p>14 litigations.</p> <p>15 A No, no.</p> <p>16 MR. TRISCHLER: And that's not even a</p> <p>17 proper instruction for you to give, so just keep</p> <p>18 putting on the robe as well as acting as an</p> <p>19 advocate. It's improper, but it doesn't appear that</p> <p>20 you're ready to stop.</p> <p>21 Q Did you -- who would have the</p> <p>22 information about your company about what revenues</p> <p>23 Emery Pharma has generated from work in nitrosamine</p> <p>24 litigation?</p> <p>25 MR. NIGH: Again, this goes outside</p>
<p style="text-align: right;">Page 63</p> <p>1 corporation?</p> <p>2 A My wife and me.</p> <p>3 Q How much of the stock do you own?</p> <p>4 A Fifty-fifty.</p> <p>5 Q I presume your wife then owns the</p> <p>6 other 50 percent?</p> <p>7 A That's correct.</p> <p>8 Q And what is her name?</p> <p>9 A Kelly Faranghi.</p> <p>10 Q Do you mind spelling that for my</p> <p>11 benefit?</p> <p>12 A Sure. It's F as in Frank</p> <p>13 A-R-H-A-N-G-I -- G-H-I, and first name K-E-L-L-Y.</p> <p>14 Q Since you and Kelly are the sole</p> <p>15 shareholders of Najafi Pharma Inc, I assume, then,</p> <p>16 that all revenues generated after expenses go to you</p> <p>17 and your wife?</p> <p>18 A That's correct.</p> <p>19 Q In connection with your work as a</p> <p>20 litigation consultant in nitrosamine litigation, are</p> <p>21 the fees that you generate and the income that you</p> <p>22 receive paid to you through the company or is this</p> <p>23 litigation work something that you do independent of</p> <p>24 Emery Pharma?</p> <p>25 A No, it's paid through the company.</p>	<p style="text-align: right;">Page 65</p> <p>1 the scope of what is allowable. You can ask about</p> <p>2 valsartan and the revenues for valsartan, but not</p> <p>3 for all nitrosamine litigations.</p> <p>4 MR. TRISCHLER: Only thing I've asked</p> <p>5 for the name of a person at the company who would</p> <p>6 have that information.</p> <p>7 A I have that information.</p> <p>8 Q So you know the exact dollar amount?</p> <p>9 I thought you said a few minutes ago you didn't know</p> <p>10 it.</p> <p>11 A No, I didn't say that.</p> <p>12 Q Let me ask about some of the records</p> <p>13 that I received specific to your valsartan work.</p> <p>14 MR. TRISCHLER: Can you display what I</p> <p>15 premarked as Exhibit No. 2, please?</p> <p>16 A Yes.</p> <p>17 Q Exhibit No. 2 looks to be some form of</p> <p>18 a retainer agreement. Do I understand that</p> <p>19 correctly?</p> <p>20 A That's correct.</p> <p>21 Q And is this the retainer agreement</p> <p>22 that confirms your engagement --</p> <p>23 A That's correct.</p> <p>24 Q You've got to let me finish the</p> <p>25 question, sir; confirms your engagement as a</p>

<p style="text-align: right;">Page 66</p> <p>1 litigation consultant for the plaintiffs in the</p> <p>2 valsartan litigation?</p> <p>3 A That's right.</p> <p>4 Q It looks like, if we go to page 4 of</p> <p>5 this exhibit, it looks like it was signed in October</p> <p>6 of 2019. Do I have that right?</p> <p>7 A That's correct.</p> <p>8 Q And somewhere in here I think you</p> <p>9 requested or your company requested a retainer of</p> <p>10 \$5,000; is that right?</p> <p>11 A I guess so, yes.</p> <p>12 Q Is that your usual retainer or would</p> <p>13 that be something that was different for this case?</p> <p>14 A It varies.</p> <p>15 Q Was that retainer paid, if you know?</p> <p>16 A Yes, it had.</p> <p>17 Q And the retainer agreement says -- I</p> <p>18 have to find the right spot, so bear with me.</p> <p>19 A All right.</p> <p>20 Q I'm looking at page 3, if you could</p> <p>21 turn there. Thank you. There is a paragraph under</p> <p>22 background and scope of work. Do you see that, sir?</p> <p>23 A Yes, I do.</p> <p>24 Q And it says you're being -- Hollis Law</p> <p>25 is engaging Ron Najafi as a consultant expert</p>	<p style="text-align: right;">Page 68</p> <p>1 manufacturing practices, right?</p> <p>2 A Yes.</p> <p>3 Q What does GLP stand for?</p> <p>4 A Good laboratory practices.</p> <p>5 Q And CGMP and GLP guidelines that you</p> <p>6 reference in this retainer guidelines specific --</p> <p>7 that would have been developed specific by you for</p> <p>8 your lab or are you referencing or intending to</p> <p>9 reference general standards for GMP and GLP?</p> <p>10 A So Emery Pharma is an FDA-registered,</p> <p>11 FDA inspected GLP, GMP compliant laboratory and we</p> <p>12 do perform work that is under GLP, GMP to those</p> <p>13 standards. It means that you maintain good</p> <p>14 laboratory notebooks. It means that your</p> <p>15 equipment -- that their products is going to be</p> <p>16 tested. It's qualified. It's calibrated. So those</p> <p>17 are some of the things that, you know, this sentence</p> <p>18 effectively promises.</p> <p>19 Q And I understand that. I guess my</p> <p>20 question was, are the guidelines that you are</p> <p>21 referring to in this retainer a guideline of general</p> <p>22 applicability for all registered labs or are they</p> <p>23 specifically developed for your lab?</p> <p>24 A No, there are a lot of general labs</p> <p>25 that contract labs could follow GLP, GMP; could be</p>
<p style="text-align: right;">Page 67</p> <p>1 witness and Emery Pharma for laboratory activities</p> <p>2 relating to valsartan NDMA, NDEA, NBMA and DMF.</p> <p>3 A That's correct.</p> <p>4 Q What is NBMA?</p> <p>5 A That's another nitrosamine impurity.</p> <p>6 Q Do you know what NBMA stands for?</p> <p>7 A Not off the top of my head, but it</p> <p>8 is -- it could be butyl nitrosol -- n-methyl butyl</p> <p>9 nitrosamine. It could be n-methyl for amino, so I</p> <p>10 have to check with my chemistry team what is part of</p> <p>11 the proposal.</p> <p>12 Q Is part of the proposal DMF; what is</p> <p>13 DMF?</p> <p>14 A DMF stands for dimethyl fumarate.</p> <p>15 Q And the second part of that or second</p> <p>16 paragraph under that background and scope section of</p> <p>17 the retainer agreement says, "While not currently in</p> <p>18 the scope of work, if any testing of valsartan pills</p> <p>19 is ordered by clients in the future, such testing</p> <p>20 will be performed under CGMP/GLP."</p> <p>21 A Right.</p> <p>22 Q Did I read that correctly?</p> <p>23 A That's correct.</p> <p>24 Q And the -- see, I'm pretty sure I know</p> <p>25 what CGMP stands for. That's current good</p>	<p style="text-align: right;">Page 69</p> <p>1 compliant with GLP, GMP and maybe not compliant with</p> <p>2 GLP, GMP and may do things under R&D condition, so</p> <p>3 it really depends on the lab.</p> <p>4 Q And who published the CGMP and GLP</p> <p>5 guidelines that are referenced in your retainer</p> <p>6 agreement?</p> <p>7 A This particular -- are you referring</p> <p>8 to this particular retainer agreement?</p> <p>9 Q Well, yes, because that's the only</p> <p>10 retainer agreement I have.</p> <p>11 A I put it together.</p> <p>12 Q I know you put it together.</p> <p>13 A I have my signature on it.</p> <p>14 Q You're not following me. Hold on.</p> <p>15 You're not following my question, sir. My question</p> <p>16 was who has published the guidelines that you make</p> <p>17 reference to in this?</p> <p>18 A The guidelines are set by the FDA, by</p> <p>19 European medical authorities, by ICH.</p> <p>20 Q And you go on to, in this retainer</p> <p>21 agreement, state that if any testing of valsartan</p> <p>22 pills is ordered in the future, such testing is</p> <p>23 going to be performed under the guidelines. Do you</p> <p>24 see what I am referring to?</p> <p>25 A Right.</p>

<p style="text-align: right;">Page 70</p> <p>1 Q Prior to the time that you entered</p> <p>2 into this retainer agreement in October of 2019, had</p> <p>3 your lab ever conducted any testing of</p> <p>4 valsartan-containing medications produced by Mylan</p> <p>5 Pharmaceuticals?</p> <p>6 A The answer is we have conducted</p> <p>7 valsartan testing prior to this retainer agreement.</p> <p>8 Q And was the valsartan testing that you</p> <p>9 conducted, was it using valsartan tablets produced</p> <p>10 by Mylan?</p> <p>11 A I don't recall.</p> <p>12 Q Was the valsartan -- and right now I</p> <p>13 am only asking you about testing you did prior to</p> <p>14 entering this agreement. Was the valsartan lab</p> <p>15 testing that was done at Emery prior to the entry of</p> <p>16 this agreement, did it involve any valsartan</p> <p>17 containing medications produced by ZHP?</p> <p>18 A I do not recall.</p> <p>19 Q Did it involve what I'll call the</p> <p>20 pre-retainer testing, okay?</p> <p>21 A Right.</p> <p>22 Q Did any valsartan testing that you</p> <p>23 made reference to that was conducted at the Emery</p> <p>24 lab involve any other valsartan-containing</p> <p>25 medications produced by Hetero?</p>	<p style="text-align: right;">Page 72</p> <p>1 chain of custody and they get it tested, and I</p> <p>2 honestly don't know. I don't pay attention to who</p> <p>3 the manufacturers are.</p> <p>4 Q So your lab has done valsartan testing</p> <p>5 of valsartan medications since entering into this</p> <p>6 retainer agreement, correct?</p> <p>7 A We have done lots of valsartan testing</p> <p>8 prior to this agreement and we've done more</p> <p>9 valsartan testing post this agreement.</p> <p>10 Q And if I understand your testimony --</p> <p>11 I am going to get into the details of it more, but</p> <p>12 if I understand your testimony so far, what you're</p> <p>13 suggesting is that as you sit here today providing</p> <p>14 testimony under oath, you're not able to tell us</p> <p>15 whose valsartan product you tested in terms of who</p> <p>16 the manufacturer was?</p> <p>17 A No, I don't have that information.</p> <p>18 Q Would there be records available in</p> <p>19 your lab records that would tell you that?</p> <p>20 A Yes, there would be records available</p> <p>21 at our lab that would tell me exactly what the</p> <p>22 manufacturers are.</p> <p>23 Q When did your lab first start doing</p> <p>24 valsartan testing?</p> <p>25 A I think around maybe May of -- April,</p>
<p style="text-align: right;">Page 71</p> <p>1 A I do not recall and if I did, it would</p> <p>2 be privileged. It would be under a different, you</p> <p>3 know, agreement with another law firm.</p> <p>4 Q Did any of the testing that you did</p> <p>5 prior to this retainer agreement involve</p> <p>6 Aurobindo-manufactured products?</p> <p>7 A I do not recall. I don't know.</p> <p>8 Q Do you recall if any of the</p> <p>9 pre-retainer valsartan testing done at your</p> <p>10 laboratory involved any valsartan-containing</p> <p>11 medications produced by any of the defendants to</p> <p>12 this litigation?</p> <p>13 A I do not recall the manufacturer's</p> <p>14 name that we tested prior to this agreement. It</p> <p>15 could have been any one of those companies.</p> <p>16 Q Since you entered into this retainer</p> <p>17 agreement and became a consultant in this valsartan</p> <p>18 litigation in October of 2019, have you ever</p> <p>19 conducted any lab testing on any valsartan</p> <p>20 medications produced by Mylan?</p> <p>21 A I do not recall. We test valsartan.</p> <p>22 We assign numbers to pills. We have very good chain</p> <p>23 of custody. We typically -- the operators who do</p> <p>24 the testing, they have no idea who is manufacturing</p> <p>25 the pills. There simply there is an ID to it and</p>	<p style="text-align: right;">Page 73</p> <p>1 May of 2019.</p> <p>2 Q What was the reason that your lab</p> <p>3 started to do valsartan testing in April or May of</p> <p>4 2019?</p> <p>5 A I think it was initiated primarily by</p> <p>6 the recall of valsartan products.</p> <p>7 Q And is it something that your lab did</p> <p>8 on its own initially or were you retained by</p> <p>9 somebody to do that testing in April and May of</p> <p>10 2019?</p> <p>11 A We were retained.</p> <p>12 Q And who retained you in April or May</p> <p>13 of 2019 to do that testing?</p> <p>14 MR. NIGH: Again, if this is</p> <p>15 privileged information and has nothing to do with</p> <p>16 this case, then I would instruct you not to answer</p> <p>17 and waive whoever else's privilege you have.</p> <p>18 A It is confidential and privileged.</p> <p>19 MR. TRISCHLER: Well, I think -- you</p> <p>20 know, in fairness, I think I am entitled to know who</p> <p>21 it was in order to determine whether there is any</p> <p>22 claim of privilege.</p> <p>23 A It was a law firm.</p> <p>24 Q Was it a law firm representing a</p> <p>25 plaintiff, representing a manufacturer, a drug</p>

<p style="text-align: right;">Page 74</p> <p>1 supplier; do you know?</p> <p>2 A It was a law firm representing</p> <p>3 plaintiffs.</p> <p>4 Q Is that firm that retained you in</p> <p>5 April or May of 2191 of the law firms that are</p> <p>6 involved in the valsartan MDL?</p> <p>7 A I don't know.</p> <p>8 Q Do you know if the lawyer for the firm</p> <p>9 that retained you is involved in the valsartan MDL?</p> <p>10 A We do the testing. We know the</p> <p>11 nitrosamine. We know the chemistry. We don't</p> <p>12 really get involved with, you know, sort of the</p> <p>13 legal aspects of what's going on.</p> <p>14 Q I understand. My question was</p> <p>15 simply -- and if you don't know you can tell me you</p> <p>16 don't know, but my question --</p> <p>17 A I don't know. I don't know, honestly.</p> <p>18 They may be involved with MDL. They may not.</p> <p>19 Q And so are you able to describe for me</p> <p>20 what type of testing you were retained to do in</p> <p>21 April or May of 2019?</p> <p>22 MR. NIGH: Let me in for a second</p> <p>23 here. I am going to object. I think all this</p> <p>24 information is privileged. I appreciate, Clem,</p> <p>25 Mr. Trischler, trying to understand who the parties</p>	<p style="text-align: right;">Page 76</p> <p>1 what the reports disclosed, just whether reports</p> <p>2 were generated.</p> <p>3 MR. NIGH: Again, privileged.</p> <p>4 MR. TRISCHLER: So you're instructing</p> <p>5 him not to answer that question?</p> <p>6 MR. NIGH: Yes.</p> <p>7 BY MR. TRISCHLER:</p> <p>8 Q Were there established lab protocols</p> <p>9 that Emery had created pursuant to which the April,</p> <p>10 May 2019 testing was conducted?</p> <p>11 MR. NIGH: Again, privileged.</p> <p>12 MR. TRISCHLER: See, Dan, I disagree</p> <p>13 with you there. If there is an established protocol</p> <p>14 that they have that's part of their everyday, work I</p> <p>15 think I'm clearly entitled to that. I'm not asking</p> <p>16 him the results of the testing, but just the</p> <p>17 protocols that were followed. Those are lab</p> <p>18 procedures. I don't think -- that's not privileged.</p> <p>19 MR. NIGH: You know, for the</p> <p>20 certification he doesn't rely on testing of the</p> <p>21 valsartan pills at all whatsoever in any of his</p> <p>22 testing that he has done, so it's outside the scope</p> <p>23 and privileged.</p> <p>24 MR. TRISCHLER: And I don't want to</p> <p>25 argue relevancy or privilege with you right now. I</p>
<p style="text-align: right;">Page 75</p> <p>1 are and I think Dr. Najafi just doesn't know whether</p> <p>2 or not they are related to MDL. I think we do know.</p> <p>3 It has no bearing on any of plaintiff's counsel and</p> <p>4 no relation to this MDL, but I don't think that he</p> <p>5 knows that. Why you ask him sitting here today.</p> <p>6 MR. TRISCHLER: I understand and I am</p> <p>7 not trying to be unfair, Daniel. I'm just trying</p> <p>8 to -- if we need to raise the issue, I'm trying to</p> <p>9 understand some of the basic facts of what was done</p> <p>10 and when so that -- and sort of making a record. I</p> <p>11 assume if we get into it later, I don't think</p> <p>12 there's any dispute that we ought to be entitled to</p> <p>13 know the basic facts of what he did so we can argue</p> <p>14 relevance and privilege to the Court, and that's all</p> <p>15 I am really trying to do here.</p> <p>16 I think the only question pending at</p> <p>17 this point is are you able to describe the type of</p> <p>18 testing that was done in April or May of 2019.</p> <p>19 MR. NIGH: No, I think that that's</p> <p>20 privileged.</p> <p>21 BY MR. TRISCHLER:</p> <p>22 Q Were reports of -- whatever testing</p> <p>23 was done, were reports generated?</p> <p>24 MR. NIGH: Again, privileged.</p> <p>25 MR. TRISCHLER: Well, I didn't ask</p>	<p style="text-align: right;">Page 77</p> <p>1 am just trying to understand the facts so that we</p> <p>2 can seek the information later, but the fact that</p> <p>3 he's not relying on it for whatever opinions he</p> <p>4 intends to offer at this stage of the proceedings is</p> <p>5 not determinative. For all we know there may be</p> <p>6 information that undermines his opinions, but we</p> <p>7 don't know until we have an opportunity to discover</p> <p>8 it.</p> <p>9 Again, the only question pending at</p> <p>10 this point -- you've made your objections where you</p> <p>11 think they are appropriate and I am not arguing any</p> <p>12 of them, Dan. I am just asking you to reconsider</p> <p>13 the objection to the question I just asked about</p> <p>14 whether there are existing lab protocols pursuant to</p> <p>15 which this work in 2019 was done. I don't think</p> <p>16 that's privileged at all.</p> <p>17 MR. NIGH: I think you asked that</p> <p>18 question a little bit differently and I think he can</p> <p>19 answer that question.</p> <p>20 MR. TRISCHLER: Tell me how you think</p> <p>21 it should be asked differently and I will accept</p> <p>22 that.</p> <p>23 MR. NIGH: No, no. I think you asked</p> <p>24 it differently. My understanding is you're asking</p> <p>25 do they have guidelines as to how this testing would</p>

<p style="text-align: right;">Page 78</p> <p>1 be conducted. That's different.</p> <p>2 MR. TRISCHLER: Well, that was --</p> <p>3 MS. HILTON: Not developed for the</p> <p>4 testing, but do they have guidelines that were in</p> <p>5 place or existing at the time of the testing.</p> <p>6 MR. TRISCHLER: Yes. That's what I'm</p> <p>7 looking for.</p> <p>8 A So what's the question?</p> <p>9 Q The question was at the time this</p> <p>10 testing was done in April or May of 2019, did your</p> <p>11 lab have existing protocols and guidelines in place</p> <p>12 that would have governed that testing.</p> <p>13 A We follow several guidelines, several</p> <p>14 procedures from FDA on testing of, basically,</p> <p>15 nitrosamines, and that's what we use. So it's</p> <p>16 established testing guideline, you know, with the</p> <p>17 full following the same guideline procedure</p> <p>18 controls.</p> <p>19 Q Do you have any information --</p> <p>20 whatever the valsartan that was tested in April or</p> <p>21 may of 2019, do you have any idea where it came</p> <p>22 from?</p> <p>23 MR. NIGH: I am going to object to</p> <p>24 privilege and instruct him not to answer. Actually,</p> <p>25 I think we have gone far beyond. I think we are</p>	<p style="text-align: right;">Page 80</p> <p>1 answer about any testing that he has done outside of</p> <p>2 this litigation.</p> <p>3 MR. TRISCHLER: Also your instruction</p> <p>4 applies to what he described and what we have been</p> <p>5 calling as the April/May 2019 testing. I think he's</p> <p>6 also indicated they have been testing valsartan on</p> <p>7 an ongoing basis.</p> <p>8 MR. NIGH: That's correct, and my</p> <p>9 instruction would apply equally to that testing that</p> <p>10 has no basis in this MDL.</p> <p>11 MR. TRISCHLER: So your position, just</p> <p>12 so I'm clear and I don't have to belabor the record,</p> <p>13 is that we can agree that the witness operates a</p> <p>14 research lab that's done testing on</p> <p>15 valsartan-containing medication for nitrosamine</p> <p>16 content on a fairly consistent basis since April and</p> <p>17 May of 2019, some of which may include</p> <p>18 valsartan-containing medications produced by the</p> <p>19 defendant in this litigation, some of which may</p> <p>20 include valsartan containing medications produced by</p> <p>21 manufacturers and suppliers that are not parties to</p> <p>22 this litigation, but your instruction is a global</p> <p>23 one that all of that testing is off limits,</p> <p>24 according to the plaintiff and that the witness will</p> <p>25 be instructed not to answer any questions at all</p>
<p style="text-align: right;">Page 79</p> <p>1 going to have to brief this at this point,</p> <p>2 Mr. Trischler, because even his last answer</p> <p>3 contained, you know, essentially privileged</p> <p>4 information. Anything that has to do with testing</p> <p>5 that has no nexus to this litigation is privileged.</p> <p>6 MR. TRISCHLER: Okay. I disagree.</p> <p>7 You've disclosed this witness as a testifying</p> <p>8 expert. He's now indicated that he conducted</p> <p>9 valsartan testing to ascertain nitrosamine levels.</p> <p>10 He did it in 2019. He's been doing it on an ongoing</p> <p>11 basis and the suggestion has nothing to do with this</p> <p>12 litigation. I think it has no factual merit</p> <p>13 whatsoever, no disrespect intended. So we obviously</p> <p>14 have a disagreement, but if --</p> <p>15 MR. NIGH: We do, and I am going to</p> <p>16 instruct him not to answer any further. I would</p> <p>17 just redirect to his opinion. It's simply not how</p> <p>18 NDMA, how much products have NDMA. His opinion</p> <p>19 boils down to valsartan-containing products that</p> <p>20 contain NDMA OR NDEA but the generic equivalent of</p> <p>21 Diovan or Exforge because they contained NDMA, NDEA,</p> <p>22 It's as limited as to that. So whatever tests that</p> <p>23 he's done in other litigations, there is no</p> <p>24 relevancy stacked on top of the fact that it's</p> <p>25 privileged. So I am going to instruct him not to</p>	<p style="text-align: right;">Page 81</p> <p>1 about it. Is that your position?</p> <p>2 MR. NIGH: I think he's answered he</p> <p>3 doesn't know which manufacturer, so that's been</p> <p>4 established already right. Other than that, my</p> <p>5 instruction would be no further testimony, and I</p> <p>6 would instruct him not to answer about any further</p> <p>7 testimony about testing that he has done, since none</p> <p>8 of that testing was done for the MDL on behalf of</p> <p>9 the MDL and has no nexus to the MDL. Actually, if</p> <p>10 we need to brief it, we can.</p> <p>11 MR. TRISCHLER: Right. I will just</p> <p>12 say we disagree. I think it's clearly relevant and</p> <p>13 probative, but we can save it for a future date. I</p> <p>14 don't want to belabor the record on it, so let me</p> <p>15 move on.</p> <p>16 MR. NIGH: I understand.</p> <p>17 BY MR. TRISCHLER:</p> <p>18 Q You talked about or I was asking you</p> <p>19 about your work in the valsartan MDL. In addition</p> <p>20 to that retainer, I wanted to ask you about some</p> <p>21 documents that I received. I received a few</p> <p>22 invoices from your firm, Doctor, and I've had those</p> <p>23 invoices marked Exhibits 3, 4, 5 and 6, okay.</p> <p>24 MR. TRISCHLER: Can you put up -- I</p> <p>25 guess we'll start with Exhibit 3.</p>

<p style="text-align: right;">Page 82</p> <p>1 A Okay.</p> <p>2 Q It looks like Exhibit 3 is an invoice</p> <p>3 that's dated August 2, 2001, correct?</p> <p>4 A That's correct.</p> <p>5 Q This that August invoice you've</p> <p>6 submitted a bill for six hours of time for document</p> <p>7 reviews that were apparently done in July of last</p> <p>8 year; is that right?</p> <p>9 A Right.</p> <p>10 Q And then Exhibit 4 is dated</p> <p>11 January 28, 2022; just last week, right?</p> <p>12 A Right.</p> <p>13 Q And there you billed, submitted an</p> <p>14 invoice for two hours worth of time that you spent</p> <p>15 back in October of last year, right?</p> <p>16 A Not October, November.</p> <p>17 Q Well, it says class certification</p> <p>18 review October 25, 2021?</p> <p>19 A Right. Right. Exactly.</p> <p>20 Q So what does that mean, class</p> <p>21 certification review October 25, 2021?</p> <p>22 A So this is the -- pertains to my</p> <p>23 expert report on the class certification primarily.</p> <p>24 Q I wasn't sure. Is there some -- I</p> <p>25 don't know what "class certification review" means.</p>	<p style="text-align: right;">Page 84</p> <p>1 dated February 1, 2022, and you've got a bill for</p> <p>2 about 15 hours of time?</p> <p>3 A It's, again, reviewing for today's</p> <p>4 call and refreshing my memory on the various</p> <p>5 citations that I'm quoting and all of that.</p> <p>6 Q Right. So it looks like you spent</p> <p>7 about 15 hours --</p> <p>8 A Right.</p> <p>9 Q -- preparing for this deposition?</p> <p>10 A Exactly.</p> <p>11 Q And when you were preparing for this</p> <p>12 deposition, who were you preparing with?</p> <p>13 A Myself --</p> <p>14 Q And --</p> <p>15 A -- and I also spent some time with the</p> <p>16 plaintiff's lawyer discussing the deposition.</p> <p>17 Q And which lawyer would that be on the</p> <p>18 plaintiff's side?</p> <p>19 A Rosemarie, Daniel, Brad and Layne.</p> <p>20 Q So I assume these invoices, then, that</p> <p>21 we have that we marked as exhibits 3 through 6 would</p> <p>22 accurately reflect the time that you spent and that</p> <p>23 you devoted to this valsartan project since you were</p> <p>24 retained in October of 2019, right?</p> <p>25 A This is not all of them. This is</p>
<p style="text-align: right;">Page 83</p> <p>1 What did you do over those hours?</p> <p>2 A The expert report that you were</p> <p>3 looking at earlier, essentially, review of</p> <p>4 documents, review -- you know, putting that</p> <p>5 together, putting the expert report together and</p> <p>6 putting the package of citations and everything that</p> <p>7 needs to be that you all have in your hands</p> <p>8 together.</p> <p>9 Q Okay. And then the other invoice that</p> <p>10 I have is Exhibit 5. It's dated January 31, 2022,</p> <p>11 which is just a few days ago, right?</p> <p>12 A Right.</p> <p>13 Q And you've got two more hours that you</p> <p>14 billed for review of class certification final</p> <p>15 declaration review in November -- on November 4,</p> <p>16 2021, right?</p> <p>17 A Right.</p> <p>18 Q I guess you spent two hours reviewing</p> <p>19 that declaration on that date?</p> <p>20 A Right, but this is reviewing a lot of</p> <p>21 the citations, reviewing the -- you know, just</p> <p>22 preparing. This is just preparation for today's</p> <p>23 call.</p> <p>24 Q Okay. And then the final invoice that</p> <p>25 I received is Exhibit 6. We marked that. It's</p>	<p style="text-align: right;">Page 85</p> <p>1 primarily just specific to this expert report that</p> <p>2 we did.</p> <p>3 Q Well, I am interested in all the time</p> <p>4 and work and billing that you have submitted in</p> <p>5 connection with your working in valsartan MDL. So</p> <p>6 this is just a drop-in the bucket?</p> <p>7 A This is a portion of the bills that we</p> <p>8 have given. We haven't shared all the bills.</p> <p>9 Q Why not?</p> <p>10 MR. NIGH: That's a legal question.</p> <p>11 We objected and provided the reasons for that</p> <p>12 objection. His opinion here today is limited on his</p> <p>13 class certification and not his liability on things.</p> <p>14 Q So let me ask you about the</p> <p>15 declaration itself. You have -- I marked the</p> <p>16 declaration as Exhibit No. 1. Do you have a copy of</p> <p>17 it there or do you need to have the --</p> <p>18 A I have it.</p> <p>19 Q You have it?</p> <p>20 A Yes, I do.</p> <p>21 Q All right. And so this is a</p> <p>22 declaration that has your name and your signature</p> <p>23 attached to it, correct?</p> <p>24 A Correct.</p> <p>25 Q And it's not on the letterhead of</p>

<p style="text-align: right;">Page 86</p> <p>1 Emery Pharma, is it?</p> <p>2 A No, it's not.</p> <p>3 Q It's not on your personal letterhead,</p> <p>4 is it?</p> <p>5 A No, it's not.</p> <p>6 Q Was this something that you personally</p> <p>7 prepared or was this prepared by the lawyers?</p> <p>8 A No, I personally prepared the</p> <p>9 document.</p> <p>10 Q Every word of this is your words?</p> <p>11 A Yes, it is.</p> <p>12 Q No help from the lawyers?</p> <p>13 A No help.</p> <p>14 Q And as I read the declaration, it</p> <p>15 appeared to me that there were two opinions</p> <p>16 contained in this declaration. The first one was</p> <p>17 that you suggest that NDMA and NDEA should not be</p> <p>18 present in any drug, am I correct that in stating</p> <p>19 that sort of opinion that you hold and you expressed</p> <p>20 in this declaration?</p> <p>21 A Please repeat your question. I lost</p> <p>22 track.</p> <p>23 Q Yeah. I was just trying to summarize</p> <p>24 what I think your opinions are that are contained in</p> <p>25 this declaration and I want to make sure I got it</p>	<p style="text-align: right;">Page 88</p> <p>1 Q No.</p> <p>2 A What's your question?</p> <p>3 Q I am trying to ask you a question. In</p> <p>4 your declaration do you offer the opinion that the</p> <p>5 presence of any nitrosamine impurity in a generic</p> <p>6 drug product renders that product not equivalent to</p> <p>7 the reference listed drug?</p> <p>8 A Absolutely.</p> <p>9 Q And do you agree that those are the</p> <p>10 opinions that you set forth in your declaration and</p> <p>11 that you intend to offer in this matter?</p> <p>12 A Absolutely.</p> <p>13 Q Are there any others?</p> <p>14 A No generic drug should contain any</p> <p>15 mutagenic compound, particularly NDMA and NDEA and,</p> <p>16 essentially, any nitroso compound. They are cohorts</p> <p>17 of concerns and their limits should be zero.</p> <p>18 Q And that was the first opinion that we</p> <p>19 went over. Other than those two opinions, are there</p> <p>20 any others that you intend to offer?</p> <p>21 A I might have opinions to offer in my</p> <p>22 full expert report which will be coming shortly, but</p> <p>23 what you see for now is what I think I have, but I</p> <p>24 will have other opinions as well.</p> <p>25 Q I'm sure we will all wait with bated</p>
<p style="text-align: right;">Page 87</p> <p>1 correct. So what I was saying was --</p> <p>2 A Yeah.</p> <p>3 Q -- in this declaration --</p> <p>4 A Yeah.</p> <p>5 Q -- you state that NDMA and NDEA should</p> <p>6 not be present in any drug. Is that an opinion that</p> <p>7 you hold?</p> <p>8 A NDMA and NDEA are carcinogenic</p> <p>9 mutagenic compound that should not be present in any</p> <p>10 drug period.</p> <p>11 Q And then the second opinion that I saw</p> <p>12 in this declaration was that you suggest that the</p> <p>13 presence of a nitrosamine impurity in a generic drug</p> <p>14 product renders that --</p> <p>15 A Could you point to that? Your screen</p> <p>16 is frozen.</p> <p>17 Q Point to what, sir?</p> <p>18 A Point to -- you're showing me a</p> <p>19 document on this screen.</p> <p>20 Q No, I wasn't. We can take the</p> <p>21 document down.</p> <p>22 A Okay.</p> <p>23 Q You have the report in front of you.</p> <p>24 A I thought you were quoting from my</p> <p>25 declaration, but go ahead.</p>	<p style="text-align: right;">Page 89</p> <p>1 breath for the next report, but at this time at this</p> <p>2 state of litigation, those two opinions are the</p> <p>3 stated opinions that you intend to offer; is that</p> <p>4 right?</p> <p>5 A Yes.</p> <p>6 MR. TRISCHLER: Dan, can we take a</p> <p>7 five minute comfort break?</p> <p>8 MR. NIGH: Yes. Let's take ten</p> <p>9 minutes.</p> <p>10 THE VIDEOGRAPHER: The time is 11:41.</p> <p>11 This concludes Media No. 2.</p> <p>12 (A recess was taken.)</p> <p>13 (After the recess the following</p> <p>14 occurred:)</p> <p>15 THE VIDEOGRAPHER: The time is now</p> <p>16 12:03. This begins Media No. 3. You may proceed.</p> <p>17 BY MR. TRISCHLER:</p> <p>18 Q Doctor, allow me to cover a few</p> <p>19 additional background issues with you, if I can. As</p> <p>20 I understand it, your background and education is in</p> <p>21 the field of chemistry, correct?</p> <p>22 A That's correct.</p> <p>23 Q I was provided with a copy of a CV.</p> <p>24 I've marked it as Exhibit 7.</p> <p>25 A Okay.</p>

<p style="text-align: right;">Page 90</p> <p>1 MR. TRISCHLER: Can someone put it up 2 for me, please. Can you go to the next page. 3 Q If you need more time, tell me and 4 continue, please. 5 A I am familiar with my CV. 6 Q All right. And is this a -- what we 7 marked as Exhibit 7 a true, correct and accurate 8 summary of your qualifications and credentials? 9 A That's correct. 10 Q In the copy of the CV that I received, 11 I did not see any list of publications. Do you 12 maintain a list of publications? 13 A It should be. It should be there. 14 Q Can you flip through? Maybe this is a 15 different one than what I had with the report. 16 A Maybe this is a different one. 17 Q Is that the end of the document there? 18 THE VIDEOGRAPHER: There are 13 pages. 19 Do you want me to keep flipping through or do you 20 want me to when you're ready for the next one? 21 MR. TRISCHLER: Yes. Keep flipping 22 through, because if it's more than five pages, then 23 it's different than one I have. 24 A Now you see the publication. 25 Q Yes. Okay. The copy that I was</p>	<p style="text-align: right;">Page 92</p> <p>1 A Correct. 2 Q Good. And what I remember reading is 3 that you obtained a bachelor's and master's in 4 organic chemistry from the University of San 5 Francisco, right? 6 A Correct. 7 Q And I think it was in 1998 you got 8 your PhD in organic chemistry from U.C. Davis? 9 A That's correct. 10 Q And after completing your PhD you went 11 to work as a research scientist for a few chemical 12 and pharmaceutical companies before starting your 13 own business around 1996? 14 A That's correct. 15 Q And the company that you started in 16 1996 was a company called CP Lab Safety; do I have 17 that right? 18 A That's correct. 19 MR. TRISCHLER: You could take the CV 20 down, sir. 21 Q How long did you run CP Lab Safety? 22 A Probably around two years, two or 23 three years. 24 Q Did CP Lab Safety develop or 25 manufacture drug products?</p>
<p style="text-align: right;">Page 91</p> <p>1 looking at did not have that. All right. Thank 2 you. 3 A What is your question? 4 Q As far as you know, this version of 5 the CV we marked as Exhibit 7 is current, up to date 6 and accurate, right? 7 A Right, as long as you can show me 8 everything else, because it sounded like you were 9 missing some parts of it. I only see two 10 publications on your exhibit. 11 Q Well, we said we can flip through the 12 rest if you like. That's why I asked if you wanted 13 to. 14 A Yes, flip through it. 15 THE VIDEOGRAPHER: This is page 6, 16 Doctor. Just let me know when you're ready for the 17 next page. 18 THE WITNESS: Yes. Go ahead. Go 19 ahead. Yes. Uh-huh. Okay. Yes. 20 THE VIDEOGRAPHER: There's two more 21 pages. 22 A Okay. I think you have everything. 23 Q So we're good? In terms of what we 24 marked as Exhibit 7 is the up to date, current and 25 accurate summary of your qualifications, right?</p>	<p style="text-align: right;">Page 93</p> <p>1 A No. 2 Q Did CP Labs hold any new drug 3 applications? 4 A No. 5 Q Did CP Labs hold any abbreviated drug 6 applications. 7 A No. 8 Q Did CP Labs hold any or were they 9 responsible for any drug master files? 10 A No. 11 Q While at CP Labs, were you or was your 12 company at all involved in the synthesis, 13 manufacture or testing of API for drug products? 14 A No. 15 Q At CP Labs did your company have any 16 role in the formulation, synthesis, manufacture, 17 production or testing of angio tensin receptor 18 blocker medications like valsartan? 19 A So at CP lab I started another 20 pharmaceutical company called NovaBay 21 Pharmaceuticals and that is immediately following CP 22 Lab and that company effectively was incubated 23 within CP Lab and within NovaBay I had multiple 24 interactions with the FDA. We manufactured product 25 according to CGMP and we put products on the market.</p>

<p style="text-align: right;">Page 94</p> <p>1 And prior to CP Lab, I worked at a pharmaceutical 2 company that was heavily involved in GMP 3 manufacturing and drug product, drug substance and 4 that one of the companies I worked for, Applied 5 Biosystems, in fact, you know, we had a challenging 6 impurity that was causing a lot of problem and I was 7 responsible for finding that impurity and solving a 8 major problem that led to an award, you know, 9 amongst 1,300 PhDs. This is back in 1994. 10 So -- but, you know, I don't have to have 11 experience in, you know, ARBs to know the molecule. 12 I can synthesize ARB personally. 13 Q Are you finished? 14 A Yes, I am. 15 Q All right. Then let me see if I can 16 get you to answer my question. At CP Labs did your 17 company have any role in the formulation, synthesis, 18 manufacture, production or testing of ARBs like 19 valsartan? 20 A No. At CP lab we did not have any ARB 21 manufacture. 22 Q You said that -- if I can unfold some 23 of that commentary that you gave me, was that CP 24 Labs was eventually folded into NovaBay 25 Pharmaceuticals, another company that you started?</p>	<p style="text-align: right;">Page 96</p> <p>1 evaporation of solvents from the fume. It's an 2 environmental product that prevents pollution 3 outside of laboratory. It prevents evaporation of 4 toxic substances, including mutagenic -- potentially 5 mutagenic compounds going into the atmosphere and 6 into the neighboring localities. And ecological 7 funnel is in use right now in, I would say, 8 90 percent of pharmaceutical companies worldwide. 9 Q When did you start NovaBay? 10 A NovaBay was incubated within CP Lab 11 around probably 1998; '97, '98 and officially it 12 became a company in the year 2000, and I took the 13 company public in 2007 and I left. I sold my shares 14 and left NovaBay in 2015 and started Emery Pharma. 15 And Emery Pharma, actually, again was incubated 16 within NovaBay starting at 2011. 17 Q Am I correct that NovaBay produces 18 antibacterial products for the eye care and skincare 19 markets? 20 A That's correct. That's some of their 21 products. 22 Q While you were at NovaBay, did the 23 company do any work on the formulation synthesis, 24 manufacture, production or testing of ARBs? 25 A We did not manufacture, synthesize,</p>
<p style="text-align: right;">Page 95</p> <p>1 A No. CP Lab is, you know, existing 2 company right now and it's a standalone company. 3 NovaBay was incubated within CP Lab and NovaBay got 4 its start from CP Lab. 5 Q So CP Lab still exists today? 6 A Yes it does. 7 Q Do you have any affiliation with CP 8 Lab? 9 A I own 50 percent of CP Lab. 10 Q Who owns the other half? 11 A My wife. 12 Q What's the business of CP Labs today, 13 do you know? 14 A CP Lab manufactures patented product 15 called ecological funnel, which is product that I 16 invented while I was at Applied Biosystem and that 17 patented product is the major product of CP Lab and 18 they manufacture it in the United States and they 19 export it around the world including China, Korea, 20 Japan and elsewhere. 21 They also distribute chemicals, distribute 22 safety product. So you can visit CPlab.com and take 23 a look at it. 24 Q What is an ecological funnel? 25 A It's a tunnel that prevents</p>	<p style="text-align: right;">Page 97</p> <p>1 formulate any ARBs at NovaBay. 2 Q Did -- while at NovaBay, did that 3 company ever prepare or submit an abbreviated new 4 drug application for any drug product? 5 A We did not prepare or submit any 6 abbreviated new drug application. However, we 7 submitted many INDs, investigation of new drug, and 8 we also submitted many 510-Ks from the drug or 9 device division of the FDA. 10 Q I guess was that because the focus at 11 NovaBay was to try to develop its own line of -- 12 A Product. 13 Q -- probial products? 14 A Right. We were not a generic 15 manufacturing -- we were not a generic 16 pharmaceutical company. 17 Q So at no time at NovaBay were you 18 involved in synthesizing API for a generic 19 formulation, correct? 20 A We could have, but that was not the 21 mission of the company. 22 Q So it was never done? 23 A Never done. 24 Q And then at some point did you say 25 Emery Pharma was intubated?</p>

<p style="text-align: right;">Page 98</p> <p>1 A Incubated.</p> <p>2 Q I'm sorry?</p> <p>3 A Incubated.</p> <p>4 Q Incubated. I said intubate. That</p> <p>5 would not be correct.</p> <p>6 A I heard "intubated."</p> <p>7 Q Right. That's what I said. I did say</p> <p>8 that. That was not correct, so I apologize.</p> <p>9 And then eventually Emery Pharma became a</p> <p>10 standalone company that you operate to this day,</p> <p>11 correct?</p> <p>12 A Correct.</p> <p>13 Q And I think that if I understand what</p> <p>14 you've previously described for us, the mission</p> <p>15 statement and the function of Emery Pharma is to</p> <p>16 provide research laboratory services that meet the</p> <p>17 CGMP and GLP standards for quality?</p> <p>18 A Emery Pharma is a FDA registered, FDA</p> <p>19 inspected DMB, GLP compliant contract research</p> <p>20 organization and our mission is to help save lives</p> <p>21 and save the environment.</p> <p>22 Q Does Emery Pharma develop or</p> <p>23 manufacture drug products?</p> <p>24 A Emery Pharma? That's not within the</p> <p>25 mission of the Emery Pharma, no. We can, but we do</p>	<p style="text-align: right;">Page 100</p> <p>1 drug applications?</p> <p>2 A That's confidential information. I</p> <p>3 wouldn't be able to share with you.</p> <p>4 Q So you'll say that you have experience</p> <p>5 helping to prepare ANDAs and NDAs, but you won't</p> <p>6 tell us who you did it for?</p> <p>7 A Yes.</p> <p>8 Q Have you ever assisted a client in</p> <p>9 preparing a DMF?</p> <p>10 A Personally, no, but some of my</p> <p>11 employees might have.</p> <p>12 Q In your career, sir, have you ever</p> <p>13 published any peer-reviewed literature related to</p> <p>14 nitrosamine impurities in pharmaceuticals?</p> <p>15 A Yes, we have. We filed a citizen</p> <p>16 petition which was previewed by FDA and the response</p> <p>17 we got from the FDA was they had agreed with our</p> <p>18 findings, so I just would consider that very</p> <p>19 peer-reviewed.</p> <p>20 Q My question wasn't have you ever</p> <p>21 submitted a citizens petition. My question was have</p> <p>22 you submitted literature for publication in a</p> <p>23 scientific journal that's been peer reviewed and</p> <p>24 accepted that related to nitrosamine impurities in</p> <p>25 pharmaceuticals?</p>
<p style="text-align: right;">Page 99</p> <p>1 not.</p> <p>2 Q Does Emery Pharma hold any new drug</p> <p>3 applications?</p> <p>4 A No, we do not. Our clients do.</p> <p>5 Q Does Emery Pharma hold any abbreviated</p> <p>6 new drug applications?</p> <p>7 A We do not, but our clients do.</p> <p>8 Q Has Emery Pharma ever prepared a DMF,</p> <p>9 submitted a DMF?</p> <p>10 A We do not, but we help our clients</p> <p>11 essentially submit DMF and NDA and IMD and we</p> <p>12 participate in their FDA meetings when necessary.</p> <p>13 Q And I'm sorry. I think it was</p> <p>14 probably due to sometimes there's sound that goes in</p> <p>15 and out in the computer. You said you help clients</p> <p>16 with submissions of what was that again?</p> <p>17 A New drug application, abbreviated new</p> <p>18 drug application; DMF filings; you know, support.</p> <p>19 Just about anything that the client needs, we help.</p> <p>20 We support them.</p> <p>21 Q And how long has Emery Pharma been in</p> <p>22 business?</p> <p>23 A Since 2011, ten years.</p> <p>24 Q Who are the clients for whom you've</p> <p>25 help submit new drug applications or abbreviated new</p>	<p style="text-align: right;">Page 101</p> <p>1 MR. NIGH: Objection. You can answer.</p> <p>2 A We have not filed any</p> <p>3 nitrosamine-related publications in a peer reviewed</p> <p>4 journals of our FDF filing.</p> <p>5 Q The list of publications that were</p> <p>6 attached to your CV that we marked as Exhibit 7, do</p> <p>7 any of them feel with nitrosamine impurities in</p> <p>8 pharmaceuticals in any manner or form?</p> <p>9 A I do not believe they do.</p> <p>10 Q Have you ever drafted a manuscript</p> <p>11 related to nitrosamine impurities in valsartan for</p> <p>12 publication in a peer review journal?</p> <p>13 A We have drafted publication regarding</p> <p>14 NDMA and nitrosamines, but not published.</p> <p>15 Q Have you submitted a manuscript for</p> <p>16 publication?</p> <p>17 A No.</p> <p>18 Q Why not?</p> <p>19 A It's confidential. It's related to</p> <p>20 another matter that we are working on related to</p> <p>21 ranitidine.</p> <p>22 Q Will you provide it to me?</p> <p>23 A Daniel? I suppose I can.</p> <p>24 MR. NIGH: We would have to see what</p> <p>25 the document is. I think he just amended his answer</p>

<p style="text-align: right;">Page 102</p> <p>1 at the end to say it's for ranitidine and your 2 question is for valsartan. 3 MR. TRISCHLER: I think the question 4 was -- 5 A It's under -- 6 MR. TRISCHLER: Hold on. Hold on. I 7 think my memory is not infallible, Daniel, but what 8 I was basically asking is whether he's ever drafted 9 a manuscript that relates to nitrosamine impurities 10 in pharmaceuticals. I may have said valsartan, but 11 my intent was broader, and so it sounds like 12 something. The question is can I see it. It's not 13 been produced thus far. 14 MR. NIGH: We would examine the 15 document before we respond and answer to that. 16 MR. TRISCHLER: Well, it was subject 17 to the notice of deposition in this case. In the 18 deposition notice served in connection with this 19 deposition, I asked that the witness come here with 20 all publications relating to nitrosamines. That 21 would clearly -- this manuscript that he's described 22 would clearly be responsive. 23 MR. NIGH: I think you had our 24 response an hour ago. 25 MR. TRISCHLER: I'm sorry. Unless you</p>	<p style="text-align: right;">Page 104</p> <p>1 Q What is it? 2 A It's sort of a summary that one of my 3 team members wrote regarding our filing of our 4 citizen petition regarding ranitidine and how we 5 came about it, how we found the problem and how we 6 reported it to the FDA and how FDA actually agreed 7 with us and responded to our petition in a positive 8 manner. So that's really just the story of that. 9 There's nothing about this that contains anything 10 about that draft publication. 11 Q So this is what we have marked as 12 Exhibit 8, is basically a press release that was 13 issued by Emery Pharma, correct? 14 A Correct. 15 Q And I think this press release is 16 available on your website? 17 A Website. It's not a press release. 18 It's a blog. 19 Q All right, but this document and this 20 disclosure is on your website -- 21 A That's correct. 22 Q -- for the public at large to view? 23 A Yes. 24 Q And in this document don't you state 25 or indicate that you're preparing a manuscript for</p>
<p style="text-align: right;">Page 103</p> <p>1 want to continue the deposition, I mean, this is my 2 chance to depose him on it. 3 MR. NIGH: I believe that 48 hours ago 4 we served our objections as clearly outside of the 5 scope of anything that is he's proffered in terms of 6 testimony in his expert here today. 7 MR. TRISCHLER: Well, as far as 8 outside the scope of his declaration, I disagree, 9 but I guess we will be taking it up again. 10 Q So you do have a manuscript -- 11 MR. NIGH: And just to be clear -- 12 sorry. Since you're saying something about taking 13 it up again, just so you understood too, I haven't 14 even looked at this document. So to the degree 15 you're asking about draft documents and 16 publications, obviously it would have potential 17 privilege as well. 18 A It's ranitidine related, but it's 19 nitrosamine. 20 Q Well, you've publicly disclosed the 21 existence of this manuscript, have you not? 22 A No. 23 Q Well, can you put up Exhibit 8 for us, 24 please. Do you recognize Exhibit 8? 25 A Yes, I do.</p>	<p style="text-align: right;">Page 105</p> <p>1 publication on the issue of nitrosamines in 2 pharmaceuticals? 3 A Right. 4 Q And if you could go to page 2 of this 5 document. 6 A Okay. 7 Q Can you highlight the second full 8 paragraph for me, please. Thank you. Are you able 9 to read that, sir? 10 A I'm reading it. Yes, I'm reading it. 11 Q So. Emery Pharma has publicly 12 disclosed that it's been testing valsartan, losartan 13 and other ARBs for nitrosamines since the early 2018 14 time period, correct? 15 A That's correct. 16 Q And there's nothing in these public 17 comments that you've made at the testing that we've 18 not been provided with it's something that's done 19 for litigation or confidential. You've told the 20 free world about it, right? 21 A We mentioned that we have been doing 22 that, but we haven't disclosed the results. The 23 results are confidential. 24 Q You are not a pathologist, true? 25 A Say that again, please?</p>

<p style="text-align: right;">Page 106</p> <p>1 Q You are not a pathologist?</p> <p>2 A Pathologist?</p> <p>3 Q That was my question.</p> <p>4 A No, I'm not a pathologist.</p> <p>5 Q Are you a medical doctor?</p> <p>6 A I'm not a medical doctor.</p> <p>7 Q Are you a toxicologist?</p> <p>8 A I'm not a toxicologist.</p> <p>9 Q Is it fair to say you're not a</p> <p>10 epidemiologist and you do not have any specialized</p> <p>11 training or expertise in the field of pharma</p> <p>12 epidemiology?</p> <p>13 A I am not a epidemiologist or any of</p> <p>14 that.</p> <p>15 Q Have you ever conducted and published</p> <p>16 any peer-reviewed research on the carcinogenicity of</p> <p>17 NDMA?</p> <p>18 A No, I have not.</p> <p>19 Q Have you ever conducted and published</p> <p>20 any peer-reviewed research on the carcinogenicity of</p> <p>21 NDEA?</p> <p>22 A No, I have not.</p> <p>23 Q Since you have no medical training, I</p> <p>24 assume you do not diagnose cancer in patients; fair</p> <p>25 to say?</p>	<p style="text-align: right;">Page 108</p> <p>1 research laboratory testing facility with a lot of</p> <p>2 experience in drug testing and impurity testing and</p> <p>3 genotoxic testing.</p> <p>4 Q Have you ever published anything or</p> <p>5 given any lectures or speeches on the critical</p> <p>6 review of the CMC sections and requirements for a</p> <p>7 abbreviated new drug application?</p> <p>8 A I have. I was invited to give a</p> <p>9 presentation at a drug impurity symposium for</p> <p>10 generic manufacturers and that presentation is</p> <p>11 actually available. It's on the -- it should be</p> <p>12 online YouTube or various other places.</p> <p>13 Q Is it referenced on your CV?</p> <p>14 A No.</p> <p>15 Q When did you speak at this symposium?</p> <p>16 A Probably early 2020, maybe mid 2020.</p> <p>17 I can't recall.</p> <p>18 Q We talked a little bit about Emery</p> <p>19 Pharma's status as an FDA registered research lab.</p> <p>20 What did you have to do in order to obtain that</p> <p>21 registration, if anything?</p> <p>22 A You basically submit an application to</p> <p>23 the FDA and you register yourself with the FDA, and</p> <p>24 as a result you become subject to FDA inspection.</p> <p>25 Q When did you -- when did your lab</p>
<p style="text-align: right;">Page 107</p> <p>1 A I am not a doctor.</p> <p>2 Q And in this litigation I understand</p> <p>3 you have not been designated as a witness on the</p> <p>4 issue of causation, true?</p> <p>5 A I am not a medical doctor.</p> <p>6 Q Right. And you're not going to</p> <p>7 testify -- well, we can agree you're going to be</p> <p>8 offering causation opinions in this matter, correct?</p> <p>9 A Explain to me what causation, what</p> <p>10 your definition of causation here.</p> <p>11 Q You're not going to be offering any</p> <p>12 opinions that exposure to NDEA or NDMA did or can</p> <p>13 cause cancer in humans?</p> <p>14 A No, I am not offering any opinion on</p> <p>15 the toxicology opinion on the NDEA or NDMA.</p> <p>16 Q Have you ever published anything on</p> <p>17 the requirements for a proper drug master file?</p> <p>18 A No, I have not published any</p> <p>19 requirement on anything on the requirements for drug</p> <p>20 master file.</p> <p>21 Q Have you ever published anything on</p> <p>22 outlining the regulatory duties and responsibilities</p> <p>23 of a generic drug manufacturer?</p> <p>24 A We're not in the publication business.</p> <p>25 We have not published anything. We are a contract</p>	<p style="text-align: right;">Page 109</p> <p>1 complete that application?</p> <p>2 A I think maybe 2016, 2015, some time</p> <p>3 frame.</p> <p>4 Q When did you obtain the registration;</p> <p>5 do you know?</p> <p>6 A No, I don't, probably within a few</p> <p>7 months.</p> <p>8 Q How many FDA inspections have taken</p> <p>9 place at your facility since?</p> <p>10 A We've had two inspections from the</p> <p>11 FDA.</p> <p>12 Q When were those inspections?</p> <p>13 A I can't recall; 2018 maybe one, 2021.</p> <p>14 Q Were there any Form 483 issues</p> <p>15 following those inspections?</p> <p>16 A In our second inspection we had a Form</p> <p>17 483 filled, yes.</p> <p>18 Q That was the most recent one in 2021?</p> <p>19 A That's right.</p> <p>20 Q What was that for?</p> <p>21 A It was primarily for, you know, making</p> <p>22 sure our data gets backed up and we have -- we do</p> <p>23 sufficient due diligence to make sure the data that</p> <p>24 we generate gets backed up into a secondary backup</p> <p>25 drive. So we have remedied that, and also to make</p>

<p style="text-align: right;">Page 110</p> <p>1 sure that our bend were open when we go to various 2 instruments, every user will have its own individual 3 log in, but we had no issues whatsoever on any of 4 our testing, any of our releases, any of our 5 products that are on the market. 6 There were just no issues on testing, but just 7 procedurally just data management, primarily backup, 8 and also specific user log-in, and both of those have 9 been remedied. 10 Q You said something that piqued my 11 curiosity, because I did not understand this to be 12 within the scope of anything you did. You said 13 something about our products. It was my 14 understanding that Emery Pharma does not manufacture 15 or sell any drug products. Am I wrong? 16 A No, you're not. We do not sell or 17 manufacture any drug product. However, we do 18 release them. So, another contract manufacturer 19 comes to us for a manufacture or a manufacturer 20 comes to us and says, please test my compound and 21 release them according to the guidance, ASP guidance 22 or GMP/GLP guidance. 23 So we officially release them and we identify 24 the drug, we identify their impurities and we release 25 them. So releasing is a terminology that's known to</p>	<p style="text-align: right;">Page 112</p> <p>1 constituted violations of the Food, Drug and 2 Cosmetic Act and its regulations as it related to 3 data management and data maintenance. 4 A What I said was the 483 -- first of 5 all, in our first inspection 2018 we had no problem, 6 no issues. In 2021 this issue came up that we need 7 to back up our data into the Cloud and it is really 8 part of the data management. And they basically 9 said we can continue our, you know, releasing 10 commercial products; we can continue our work. We 11 just need a commitment for you to get that done; and 12 since then we have gotten it done. 13 Q And so were any warning letters issued 14 following 483s? 15 A No. 16 Q Did -- what is Emery Pharma's status 17 with the FDA today? 18 A We are in the process of making those 19 data managements happen and they're completely 20 satisfied with that. 21 Q And so one of the things I take it you 22 learned from that most recent inspection, if not 23 earlier, was that data management, data preservation 24 and documentation are extremely important as it 25 relates to product testing, product release and</p>
<p style="text-align: right;">Page 111</p> <p>1 the FDA. It means it is ready to be sold into the 2 market. 3 Q Okay. And what you've suggested to me 4 is that in connection with the 2021 inspection, FDA 5 issued a 483 to Emery Pharma finding that certain 6 aspects of it or recordkeeping did not comply with 7 good laboratory practices, correct? 8 A What I said was that certain parts of 9 our data backup, data storage and backup did not 10 comply with the regs, and really it was a risk 11 management issue and their question was what happens 12 if there is an earthquake and then we lose all the 13 data. 14 So it needs to be backed up into the cloud so 15 in case of an earthquake, in case of fire we have 16 data that we can go back to. 17 Q Right. A form 483 is issued by an FDA 18 inspector after an inspection when that investigator 19 observes any condition that in his or her judgment 20 might constitute a violation of the Food, Drug, and 21 Cosmetic Act or its related regulations, right? 22 A That's correct. 23 Q And so what you're telling me is that 24 in 2021, your FDA-registered lab was found to have 25 conditions that in the opinion of the investigator,</p>	<p style="text-align: right;">Page 113</p> <p>1 product validation measures. 2 A Data storage and back up are important 3 primarily -- you know, it's part of their risk 4 management strategy data integrity program making 5 sure the data is always there. You know, if God 6 forbid the facility catches fire or there is an 7 earthquake, we want to make sure the client's data 8 are there somewhere else. And that's something that 9 we had a backup system on the premises, but that was 10 not acceptable to them. 11 Q So, understanding the importance of 12 data preservation -- 13 A Into the cloud. They wanted an offer 14 side data storage. 15 Q Let me ask my question, please. 16 A Sorry. 17 Q You're understanding the importance of 18 data preservation, I'm sure, then, you can tell us 19 with absolute certainty that all of the records -- 20 that there will be records relating to all of the 21 valsartan testing that your lab has been doing since 22 early 2018, correct? 23 A That includes every data preservation 24 that that we have ever generated needs to including 25 valsartan that needs to have it back, have a back up</p>

<p style="text-align: right;">Page 114</p> <p>1 outside of our facility.</p> <p>2 Q That would mean you'd have data on the</p> <p>3 acquisition of samples, correct?</p> <p>4 A Data on everything; acquisition. You</p> <p>5 know even if somebody deletes the data or what have</p> <p>6 you, everything needs to be backed up.</p> <p>7 Q And so it needs to be backed up and</p> <p>8 you've done that on the valsartan testing you have</p> <p>9 data on acquisition of samples, correct?</p> <p>10 A Acquisition of all samples including</p> <p>11 valsartan. All samples need to have an off site</p> <p>12 backup facility.</p> <p>13 Q You'll have data of custody for all</p> <p>14 valsartan samples?</p> <p>15 A Yes, we do.</p> <p>16 Q You'll have standard point operating</p> <p>17 procedures and policies outlining the protocol that</p> <p>18 weren't followed in connection with the test methods</p> <p>19 that were used on the valsartan products, right?</p> <p>20 A As an FDA registered, FDA inspected</p> <p>21 GLP/gmp-compliant lab, everything we do is SOP</p> <p>22 driven. So we have SOP's on everything.</p> <p>23 Q Because you can't conduct a test and</p> <p>24 then develop the protocol later, right?</p> <p>25 A No.</p>	<p style="text-align: right;">Page 116</p> <p>1 A So initially the valsartan issue was</p> <p>2 brought to our attention by a pharmacy out of</p> <p>3 Connecticut called Valisure. I think we mentioned</p> <p>4 their name in some of our blogs and big releases and</p> <p>5 they brought it to our attention. They wanted to</p> <p>6 test valsartan and they wanted us to test it for</p> <p>7 them. They had some testing mechanisms and they</p> <p>8 wanted us to confirm that. We did draw some samples</p> <p>9 for them, some pills and we did confirm that.</p> <p>10 That's our beginning of our engagement in the</p> <p>11 valsartan arena and that was in 2018.</p> <p>12 In 2019 we got engaged by law firm that is not</p> <p>13 on this call, I believe, and they are -- so a lot of</p> <p>14 the work we did relates to that but, yes, 2018 was</p> <p>15 our initial work with valsartan.</p> <p>16 Q And so -- thank you. That makes more</p> <p>17 sense to me now. So the initial work that your lab</p> <p>18 was doing with respect to analysis of valsartan was</p> <p>19 done at the request of Valisure, not a lawyer?</p> <p>20 A No.</p> <p>21 Q Bad question on my part.</p> <p>22 A That's correct. The initial work we</p> <p>23 did on valsartan was done at the request of</p> <p>24 Valisure.</p> <p>25 Q And you would have, consistent with</p>
<p style="text-align: right;">Page 115</p> <p>1 MR. NIGH: Objection.</p> <p>2 Q So you would be able to provide us</p> <p>3 with a protocol pursuant to which all this testing</p> <p>4 was done, correct?</p> <p>5 A If it's not privileged, yes.</p> <p>6 Q And do you have -- and you certainly</p> <p>7 have all the test results for all of valsartan</p> <p>8 samples that have been tested since the early 2018,</p> <p>9 right?</p> <p>10 A Absolutely. We have the test results</p> <p>11 and we have reports, everything. If it is not</p> <p>12 privileged, it would be available.</p> <p>13 Q I'll represent to you that the</p> <p>14 valsartan issue came to the attention of the FDA in</p> <p>15 June of 2018.</p> <p>16 A Right.</p> <p>17 Q And your public statements that -- one</p> <p>18 of which we marked as Exhibit 8 is you started</p> <p>19 testing valsartan in early 2018. Are you suggesting</p> <p>20 that you were doing valsartan testing for</p> <p>21 nitrosamines prior to the time the FDA was even</p> <p>22 aware that there was a potential issue?</p> <p>23 MR. NIGH: Form objection.</p> <p>24 THE WITNESS: Should I answer?</p> <p>25 MR. NIGH: Yes.</p>	<p style="text-align: right;">Page 117</p> <p>1 your labs, stated desire to follow good laboratory</p> <p>2 practices, you would have all of the chain of</p> <p>3 custody sample, acquisition data, protocol data,</p> <p>4 test validation data and testing summaries from that</p> <p>5 Valisure work?</p> <p>6 A Yes, I do.</p> <p>7 Q None of which has been provided to me,</p> <p>8 right?</p> <p>9 A I don't believe so.</p> <p>10 Q Do you know what the results of that</p> <p>11 work was, what nitrosamine did you test and what</p> <p>12 were the results?</p> <p>13 A You know, I wasn't sure if any of</p> <p>14 these things are subject of our -- you know, my</p> <p>15 declaration, but the results were very high levels</p> <p>16 of nitrosamines, high levels of NDMA in the</p> <p>17 thousands of nanograms.</p> <p>18 Q Do you know whose valsartan you were</p> <p>19 testing?</p> <p>20 A No.</p> <p>21 Q In 2018 at the request of Valisure?</p> <p>22 A No, I don't. We have records of that.</p> <p>23 We should be able. Right off the bat, I don't. It</p> <p>24 might have been Mylan, Teva, Aurobindo, a number of</p> <p>25 manufacturers we might have been testing.</p>

<p style="text-align: right;">Page 118</p> <p>1 Q If we go back to your declaration for</p> <p>2 a minute -- bear with me a minute. My exhibits</p> <p>3 disappeared from my screen, so we have to find it</p> <p>4 again. If we go to your declaration, we marked it</p> <p>5 as Exhibit No. 1?</p> <p>6 A Would you mind? I'd like to take a</p> <p>7 quick break, five minute break.</p> <p>8 MR. NIGH: Yeah, let's take a ten</p> <p>9 minute break.</p> <p>10 THE WITNESS: Ten minute break? Okay.</p> <p>11 THE VIDEOGRAPHER: The time is 12:47.</p> <p>12 This ends Media 3.</p> <p>13 (A recess was taken.)</p> <p>14 (After the recess the following</p> <p>15 occurred:)</p> <p>16 THE VIDEOGRAPHER: The time is now</p> <p>17 1:00. This begins Media 4. You may proceed.</p> <p>18 BY MR. TRISCHLER:</p> <p>19 Q I wanted to ask you a couple followup</p> <p>20 questions on some of the issues that we covered</p> <p>21 before the last break, Doctor. We talked about the</p> <p>22 2021 FDA inspection of Emery Pharma. Do you recall</p> <p>23 that?</p> <p>24 A Yes.</p> <p>25 Q And what I wasn't clear about is what</p>	<p style="text-align: right;">Page 120</p> <p>1 testing valsartan before the FDA was even aware of</p> <p>2 an issue?</p> <p>3 A So, you know, to be very frank to you,</p> <p>4 I don't know whether it was done before FDA official</p> <p>5 recall or after. I would have to check on that, but</p> <p>6 I was contacted by the president of Valisure David</p> <p>7 Light and he wanted us to check the levels of NDMA</p> <p>8 in valsartan.</p> <p>9 Q And you agreed to do that at his</p> <p>10 request?</p> <p>11 A And he had data already. He also had</p> <p>12 GCMS data that showed high levels of NDMA genotoxic</p> <p>13 compound, and so I was very concerned because</p> <p>14 actually my mom was taking valsartan a few years</p> <p>15 ago, so I agreed to do the work. We might not have</p> <p>16 even charged them.</p> <p>17 I think we probably charged them, I don't</p> <p>18 know, but we ran the same pills that they had ran and</p> <p>19 we corroborated their data that indeed there were</p> <p>20 high levels of NDMA in valsartan, and we might have</p> <p>21 tested for NDEA as well. I'm not sure.</p> <p>22 Q What test method did you utilize</p> <p>23 during that initial testing?</p> <p>24 A We used two or three official FDA</p> <p>25 methods that has been published. I think we used</p>
<p style="text-align: right;">Page 119</p> <p>1 is the current status of that 483, is it open or</p> <p>2 closed?</p> <p>3 A It's in the process of closing,</p> <p>4 because what happens is you're working toward</p> <p>5 getting, basically, backup system, Cloud system</p> <p>6 essentially working, you know, and validated an all</p> <p>7 of that. So that's been in the process of</p> <p>8 implementation and validation as we speak.</p> <p>9 Q So "in the process" means that it's</p> <p>10 still open?</p> <p>11 A It's still open.</p> <p>12 Q And is your lab on OAI status?</p> <p>13 A What's OAI?</p> <p>14 Q Official action indicated, I think is</p> <p>15 what it stands for.</p> <p>16 A I have to check with my QA people.</p> <p>17 Q Was an establishment inspection report</p> <p>18 issued; do you know?</p> <p>19 A I don't know.</p> <p>20 Q What -- and then going back to your</p> <p>21 early valsartan work in the early part of 2018, you</p> <p>22 said that that was prompted by a contact from</p> <p>23 Valisure that asked you to do some testing. Can you</p> <p>24 tell me who or what information you received from</p> <p>25 Valisure that caused them to be interested in</p>	<p style="text-align: right;">Page 121</p> <p>1 one of those methods.</p> <p>2 Q Well, the FDA didn't publish -- this</p> <p>3 is the thing that's confusing to me trying to piece</p> <p>4 together the timeline. FDA didn't publish a test</p> <p>5 method for nitrosamine testing until the fall of</p> <p>6 2018.</p> <p>7 A Right.</p> <p>8 MR. NIGH: Form objection.</p> <p>9 Q So that's why I asked what test method</p> <p>10 were you and Valisure running.</p> <p>11 A I would have to get that. I don't</p> <p>12 know. For the purpose of this deposition I really</p> <p>13 was not prepared to discuss any of that, but I am</p> <p>14 not prepared. It's not in my declaration.</p> <p>15 Q So let's go to the declaration, if I</p> <p>16 can. It's paragraph -- first part I want to talk to</p> <p>17 you about is paragraph 2 of the declaration I think</p> <p>18 you said you have in front of you, Doctor.</p> <p>19 A If you want me to elaborate on that, a</p> <p>20 lot of that was published in citizen petition by</p> <p>21 Valisure and I think some of our data I think he</p> <p>22 mentioned the data levels and all of that and the</p> <p>23 methods may be actually there as well.</p> <p>24 Q Were you talking about the Valisure</p> <p>25 petition relating to ranitidine?</p>

<p style="text-align: right;">Page 122</p> <p>1 A Valsartan. I think they did have</p> <p>2 something on valsartan as well.</p> <p>3 Q Did you ever file a citizens petition</p> <p>4 related to valsartan?</p> <p>5 A No.</p> <p>6 Q And when I say "you," I also mean</p> <p>7 Emery Pharma?</p> <p>8 A No.</p> <p>9 Q You think Valisure did?</p> <p>10 A Maybe I'm mistaken. I think they</p> <p>11 have. You can Google it. I may be mixing it with</p> <p>12 their citizen petition relating to ranitidine.</p> <p>13 Q I'm glad you brought it up, because it</p> <p>14 sort of led to another question that I had that</p> <p>15 wasn't clear to me.</p> <p>16 You were quick to tell me that part of the</p> <p>17 mission statement of Emery Pharma is to save lives</p> <p>18 and preserve the environment. Do you remember</p> <p>19 telling me that?</p> <p>20 A FDA -- I mean Emery Pharma's mission</p> <p>21 is to helping our client save lives and save the</p> <p>22 environment.</p> <p>23 Q And that was part of the rationale</p> <p>24 behind your issuance or decision to prepare and</p> <p>25 submit a citizens petition relating to ranitidine?</p>	<p style="text-align: right;">Page 124</p> <p>1 expense.</p> <p>2 Q Is that your second citizens petition</p> <p>3 then that you were submitting?</p> <p>4 A Yes.</p> <p>5 Q Have there been any others since then?</p> <p>6 A No.</p> <p>7 Q And you said Valisure was making a lot</p> <p>8 of noise about valsartan, but have you ever seen a</p> <p>9 citizens petition from them?</p> <p>10 A I don't recall.</p> <p>11 Q With regard to valsartan?</p> <p>12 A My memory is failing. I think -- I</p> <p>13 don't think valsartan -- I mean, you guys can google</p> <p>14 it, whether Valisure filed any citizen petition on</p> <p>15 valsartan. I don't think so. I think they just</p> <p>16 made a lot of press release, but I think the</p> <p>17 valsartan was removed from the market primarily due</p> <p>18 to Novartis finding genotoxic compound NDMA in</p> <p>19 valsartan from GMP and then effectively FDA was</p> <p>20 alerted. I think that's how the things kind of --</p> <p>21 how sort of everything fell into the, you know,</p> <p>22 basically the recall.</p> <p>23 Q Did you have any -- have you ever had</p> <p>24 any communications with Novartis about valsartan</p> <p>25 testing?</p>
<p style="text-align: right;">Page 123</p> <p>1 A We filed -- a lot of the work we did</p> <p>2 on ranitidine was done at our own expense, at our</p> <p>3 own behest primarily for the safety of the public.</p> <p>4 And we do that all the time; public comes to us and</p> <p>5 they want us to look at something. If they don't</p> <p>6 have the proper funding, we do it at pro bono and we</p> <p>7 check the drug for various impurities and problems.</p> <p>8 Q But the work you're doing in</p> <p>9 ranitidine and valsartan is not pro bono, is it?</p> <p>10 A So some of the work may be pro bono.</p> <p>11 A lot of the work that we did on ranitidine citizen</p> <p>12 petition, almost 100 percent of the work that was</p> <p>13 done for citizen petition was pro bono.</p> <p>14 Q Okay. Why did you never submit a</p> <p>15 citizens petition with respect to valsartan?</p> <p>16 A I think there wasn't any necessity for</p> <p>17 that. I think there was -- you know, obviously</p> <p>18 valsartan, it was recalled and I think Valisure was</p> <p>19 making a lot of noise, so it was already the public</p> <p>20 was alerted. And my goal as the CEO of Emery Pharma</p> <p>21 is if there is a problem with a drug, I will alert</p> <p>22 the FDA through some form of petition, and we</p> <p>23 recently actually filed a citizen petition on</p> <p>24 vitamin B6. You may be taking vitamin B6. You may</p> <p>25 want to read it; and, again, entirely at our own</p>	<p style="text-align: right;">Page 125</p> <p>1 A None.</p> <p>2 Q Have you ever had any communications</p> <p>3 with Novartis about Diovan testing?</p> <p>4 A None.</p> <p>5 Q Have you ever had any communications</p> <p>6 with Novartis about Exforge testing?</p> <p>7 A None.</p> <p>8 Q So going to paragraph 2 of your</p> <p>9 disclosure or declaration -- excuse me, I want to</p> <p>10 ask you about the last sentence in particular where</p> <p>11 you talk about the methodologies that you employed</p> <p>12 in formulating your opinions in this case and you</p> <p>13 write, "These methodologies used in formation of my</p> <p>14 opinions are also used by Emery Pharma in making</p> <p>15 recommendations to our pharmaceutical clients." Did</p> <p>16 I read that correctly?</p> <p>17 A Yes. Just let me read it. Yes, I</p> <p>18 agreed with that.</p> <p>19 Q And based on what you already told me,</p> <p>20 I take it you're not going to tell me who your</p> <p>21 pharmaceutical clients are you are referring to in</p> <p>22 paragraph 2?</p> <p>23 A I cannot. We are under</p> <p>24 confidentiality.</p> <p>25 Q So you can suggest that you're</p>

<p style="text-align: right;">Page 126</p> <p>1 following a methodology that you employ about your</p> <p>2 clients but then conveniently not tell me who the</p> <p>3 clients are, right?</p> <p>4 A We are under obligation from the</p> <p>5 clients not to disclose their name.</p> <p>6 MR. NIGH: Form objection.</p> <p>7 Q Are any of these clients defendants to</p> <p>8 the ranitidine litigation?</p> <p>9 A No.</p> <p>10 Q Are any of them defendants to the</p> <p>11 metformin litigation?</p> <p>12 A No.</p> <p>13 Q Are any of them defendants to this</p> <p>14 litigation, if you know?</p> <p>15 A No.</p> <p>16 Q Are any of the unknown undescribed</p> <p>17 clients that you make reference to, are any of them</p> <p>18 generic drug manufacturers?</p> <p>19 A No.</p> <p>20 Q Did any of them manufacture ARBs?</p> <p>21 A No.</p> <p>22 Q So you don't have any clients that you</p> <p>23 would be advising on the contents of an abbreviated</p> <p>24 new drug application, correct?</p> <p>25 A We do have clients that we advised on</p>	<p style="text-align: right;">Page 128</p> <p>1 drugs that their products are adulterated if their</p> <p>2 impurity profiles do not match the RLD?</p> <p>3 A I have told our clients that if their</p> <p>4 impurity profile contains a genotoxic compound, we</p> <p>5 will let them know.</p> <p>6 Q Thanks. That wasn't my question. My</p> <p>7 question is have you ever told your clients that</p> <p>8 they will be producing an adulterated generic</p> <p>9 product if they have an impurity profile that does</p> <p>10 not match the RLD; is that advice that you've ever</p> <p>11 given to your pharmaceutical clients in the real</p> <p>12 world?</p> <p>13 A Okay. So, here is my answer. If</p> <p>14 their impurity profile -- you know, their impurity</p> <p>15 profile may not match the RLD. However, if their</p> <p>16 impurity profile contains genotoxic compound, we</p> <p>17 will let them know and we will help them to prevent</p> <p>18 formation of genotoxic compound.</p> <p>19 Q Okay. That's fair. So the mere</p> <p>20 differences in the impurity profile alone does not</p> <p>21 make a drug adulterated?</p> <p>22 A Right.</p> <p>23 MR. NIGH: Form objection.</p> <p>24 A Mere --</p> <p>25 THE WITNESS: Can I respond, Daniel?</p>
<p style="text-align: right;">Page 127</p> <p>1 the contents of new drug application and abbreviated</p> <p>2 new drug application. However, none of them are the</p> <p>3 defendants. None of them are the plaintiffs. None</p> <p>4 of them are manufacturing ARBs as far as I know and,</p> <p>5 you know, these are -- we work on mostly branded</p> <p>6 products, some generic, sort of modified generic,</p> <p>7 branded generic but nothing to do with ARBs.</p> <p>8 Q Well, what generic -- excuse me. What</p> <p>9 generic products are you working on with generic</p> <p>10 drug manufacturers?</p> <p>11 A I can't think of it right now. I mean</p> <p>12 a number of them -- there are a number of products</p> <p>13 that we are working on.</p> <p>14 Q Well, if these products have a patent</p> <p>15 there is no secrecy to the identity of the active</p> <p>16 pharmaceutical ingredient that you're working on</p> <p>17 with the --</p> <p>18 A I can't recall off the top of my head</p> <p>19 what generics we're working on.</p> <p>20 Q So as you sit here today you can't</p> <p>21 tell me a single generic product you're advising a</p> <p>22 client about?</p> <p>23 A No.</p> <p>24 Q Have you ever told any of your</p> <p>25 pharmaceutical clients who manufactured generic</p>	<p style="text-align: right;">Page 129</p> <p>1 MR. NIGH: Yes.</p> <p>2 A A mere difference -- we have repeated</p> <p>3 this question many times. I will repeat it.</p> <p>4 Hopefully you guys can go back and see I am very</p> <p>5 consistent. Mere difference in the impurity profile</p> <p>6 so long as there is no genotoxic compound, it's</p> <p>7 fine.</p> <p>8 Q And the fact of the matter is the FDA</p> <p>9 permits variability in purity, size, strength and</p> <p>10 other parameters when evaluating an abbreviated new</p> <p>11 drug application, agreed?</p> <p>12 A FDA allows variability in the impurity</p> <p>13 profile with respect to the reference listed drug as</p> <p>14 long as it does not contain genotoxic compound --</p> <p>15 Q And we talked about --</p> <p>16 A -- namely nitrosamines.</p> <p>17 Q We talked about the acceptance</p> <p>18 criteria for impurities as published in the USP</p> <p>19 being no more than 0.1 percent. Do you remember</p> <p>20 that?</p> <p>21 A I remember the acceptance criteria of</p> <p>22 the USP not showing any NDMA and not having any</p> <p>23 limits on the NDMA. To me that means zero NDMA.</p> <p>24 Q So the fact that what the USP monitor</p> <p>25 says is that unknown impurities can be no more than</p>

<p style="text-align: right;">Page 130</p> <p>1 0.1 percent, right?</p> <p>2 A Unknown non genotoxic impurities can</p> <p>3 be around .1 percent or a little higher.</p> <p>4 Q But what you're saying is the</p> <p>5 monograph itself is silent as to genotoxic</p> <p>6 impurities, correct?</p> <p>7 A Their silence is because they assume</p> <p>8 zero NDMA. They assume zero genotoxic brought.</p> <p>9 Q And that's written nowhere in the</p> <p>10 monograph itself or in any USP publication, correct?</p> <p>11 A Exactly. Because it's not written, it</p> <p>12 means it should be nonexistent.</p> <p>13 Q And --</p> <p>14 A Because the RLD was nonexistent,</p> <p>15 because the Diovan and Exforge had no NDMA.</p> <p>16 Q Are you aware of any drug manufacturer</p> <p>17 anywhere in the world that was doing</p> <p>18 nitrosamine-specific impurity testing prior to FDA's</p> <p>19 notification of the potential for nitrosamine?</p> <p>20 A Yes, I am. I am aware.</p> <p>21 Q In 2018?</p> <p>22 A Yes, I am aware of a pharmaceutical</p> <p>23 company that does test for NDMA.</p> <p>24 Q And who is that?</p> <p>25 A Novartis, at least one which is</p>	<p style="text-align: right;">Page 132</p> <p>1 think you can Google it. You should be able to see</p> <p>2 Novartis. Just type in Novartis nitrosamine</p> <p>3 impurity. I think you will run into chemical</p> <p>4 engineering news. I might have been cited there was</p> <p>5 well.</p> <p>6 Q Didn't you develop specialized test</p> <p>7 methods to test for nitrosamines in the latter parts</p> <p>8 of 2018 and 2019?</p> <p>9 A I don't believe so.</p> <p>10 MR. NIGH: Objection. Outside the</p> <p>11 scope.</p> <p>12 A I don't believe so. I think we used a</p> <p>13 standard nitrosamine methodology.</p> <p>14 Q Did you develop a liquid LCMS method?</p> <p>15 A We did. We developed our own LCMS</p> <p>16 method primarily not for valsartan, but for other</p> <p>17 drugs.</p> <p>18 Q For Zantac?</p> <p>19 A Yes.</p> <p>20 Q So if we look at --</p> <p>21 A And beyond Zantac. We also tested</p> <p>22 probably 20 other drugs as well.</p> <p>23 Q Twenty other drugs for nitrosamines?</p> <p>24 A Yes.</p> <p>25 Q How did you pick what 20 drugs you</p>
<p style="text-align: right;">Page 131</p> <p>1 Novartis.</p> <p>2 Q How do you know -- excuse me. How do</p> <p>3 you know what test methods Novartis was using prior</p> <p>4 to June of 2018, what's your source of information?</p> <p>5 MR. NIGH: Outside the scope.</p> <p>6 A Prior to 2015 -- sorry, 2018, all I am</p> <p>7 aware is that Novartis discovered the NDMA in the</p> <p>8 ZHP product and it's because they were looking for</p> <p>9 it. They found it. They were testing it. They had</p> <p>10 space and they saw the impurity and identified the</p> <p>11 impurity. It takes no more than 10 minutes by</p> <p>12 running a GCMS to identify NDMA.</p> <p>13 Q My question is what is your source of</p> <p>14 information that Novartis was doing nitrosamine</p> <p>15 testing prior to June --</p> <p>16 A Public information.</p> <p>17 MR. NIGH: Outside the scope.</p> <p>18 Q Can you cite me to that public</p> <p>19 information, because I've never seen it.</p> <p>20 MR. NIGH: Outside the scope.</p> <p>21 A European medical authority has written</p> <p>22 about it. It was to, you know, basically -- I think</p> <p>23 that's part of EMEA in one of their reports I recall</p> <p>24 seeing it that they mentioned that Novartis saw it</p> <p>25 or maybe it was chemical engineering news, but I</p>	<p style="text-align: right;">Page 133</p> <p>1 were going to test?</p> <p>2 A We look at structural clues. You look</p> <p>3 at structural clues in a pharmaceutical molecule and</p> <p>4 you say this molecule could be prone to NDMA</p> <p>5 formation and that's called structural clues. If</p> <p>6 someone skilled in the art of chemistry looks at</p> <p>7 valsartan synthesis, there are -- it's shouting.</p> <p>8 That synthetic route is shouting that it's going to</p> <p>9 be forming a NDMA. We use those kinds of structural</p> <p>10 clues to look at other compounds to see whether they</p> <p>11 form NDMA or not.</p> <p>12 Q What are the 20 other drugs you</p> <p>13 tested?</p> <p>14 A I can't -- off the top of my head I</p> <p>15 can't recall.</p> <p>16 Q Can you recall any of them?</p> <p>17 A We looked at -- obviously we looked at</p> <p>18 nizatidine, which is a cousin of ranitidine. We</p> <p>19 looked at famotidine, which is also an anti-acid.</p> <p>20 We looked at a whole bunch of antacids, you know,</p> <p>21 and we might have looked at some over-the-counter</p> <p>22 sort of diphenyl hydramine; you know, things like</p> <p>23 that.</p> <p>24 MR. TRISCHLER: I'm sorry. I need to</p> <p>25 take a break. I've got something I need to take</p>

<p style="text-align: right;">Page 134</p> <p>1 care of. I had an appointment scheduled for 4:30</p> <p>2 that I realize I'm going to have to cancel, so I</p> <p>3 need a couple minutes to take care of that. Sorry,</p> <p>4 Dan.</p> <p>5 MR. NIGH: What's the problem? Let's</p> <p>6 take a ten minute break.</p> <p>7 THE VIDEOGRAPHER: The the time is</p> <p>8 4:24. We are going off the record.</p> <p>9 (A recess was taken.)</p> <p>10 (After the recess the following</p> <p>11 occurred:)</p> <p>12 THE VIDEOGRAPHER: The time is now</p> <p>13 1:36. We're back on the video record.</p> <p>14 BY MR. TRISCHLER:</p> <p>15 Q So, Doctor, you have told me that it</p> <p>16 is -- that it's your opinion that a drug company</p> <p>17 should not sell a product with any nitrosamines,</p> <p>18 correct?</p> <p>19 A That's what I said.</p> <p>20 Q And we talked about the fact that the</p> <p>21 regulations allow unknown impurities as high as</p> <p>22 300,000 nanograms for a 320-milligram tablet</p> <p>23 product, you interpret that requirement that USP</p> <p>24 specification as saying it applies only to non geo</p> <p>25 toxic?</p>	<p style="text-align: right;">Page 136</p> <p>1 MR. NIGH: Form objection.</p> <p>2 A Let me explain. So requirement for</p> <p>3 genotoxic impurities are far lower than regular</p> <p>4 impurities. So you must have a lot less genotoxic</p> <p>5 impurities in your drug and the levels are listed.</p> <p>6 In the case of specifically nitrosamines and</p> <p>7 specifically NDMA, the requirements should be zero.</p> <p>8 Q And you indicated that you were aware</p> <p>9 of at least one company prior to 2018 that was</p> <p>10 testing its product and making sure that its</p> <p>11 valsartan nitrosamine levels were zero, and that</p> <p>12 company was Novartis?</p> <p>13 MR. NIGH: Form objection.</p> <p>14 A As far as I know, there may be many,</p> <p>15 many more companies testing their compounds for</p> <p>16 nitrosamines, but as far as I can tell from,</p> <p>17 basically, public records, you know, NDMA --</p> <p>18 obviously Novartis looked for NDMA. Novartis found</p> <p>19 NDMA in their API, and I can only give you my</p> <p>20 opinion that Novartis perhaps -- they buy a lot of</p> <p>21 APIs from China and India. Perhaps they look for</p> <p>22 NDMA in every API they buy.</p> <p>23 Q And do you -- you indicated that or</p> <p>24 you offered the opinion that a drug company that</p> <p>25 sells a pharmaceutical product that contains a</p>
<p style="text-align: right;">Page 135</p> <p>1 A Genotoxic.</p> <p>2 MR. NIGH: Form objection.</p> <p>3 Q Right. It applies only to non</p> <p>4 genotoxic?</p> <p>5 MR. NIGH: Form objection.</p> <p>6 A I don't understand your question. My</p> <p>7 apologies. Could you repeat?</p> <p>8 Q Yes, I will ask again.</p> <p>9 A Could you ask a specific question?</p> <p>10 Q I will ask it again. I was trying to</p> <p>11 make sure I understood your testimony. I think I</p> <p>12 do, but what you've told us is the USP specification</p> <p>13 that allows for unidentified impurities to be as</p> <p>14 high as 300,000 nanograms in a 320 milligram product</p> <p>15 only applies to non genotoxic impurities?</p> <p>16 MR. NIGH: Form objection.</p> <p>17 A That applies to non genotoxic</p> <p>18 impurities.</p> <p>19 Q Right. If I misspoke, I apologize.</p> <p>20 A Right.</p> <p>21 Q That's what I understood, and that's</p> <p>22 because you interpret the absence of any</p> <p>23 specification in USP as a dictate or a mandate that</p> <p>24 the requirement for genotoxic impurities must be</p> <p>25 zero?</p>	<p style="text-align: right;">Page 137</p> <p>1 genotoxic impurity at any level or any concentration</p> <p>2 is not equivalent to the reference listed drug</p> <p>3 because the reference listed drug does not have</p> <p>4 genotoxic impurities, right?</p> <p>5 MR. NIGH: Form objection. You could</p> <p>6 answer.</p> <p>7 A The genotoxic drugs, you know, have</p> <p>8 limits that they need to abide by in an active</p> <p>9 pharmaceutical ingredients and there are specific</p> <p>10 numbers and the numbers, Clem, is not 300,000 parts</p> <p>11 per million. It's in the hundreds of parts per</p> <p>12 million, maybe even much less.</p> <p>13 In the case of nitroso, nitrosamines and the</p> <p>14 n-dimethyl nitrosamine the requirements are zero</p> <p>15 because this is a genotoxic, DNA reactive,</p> <p>16 cancer-causing molecule. And furthermore, FDA says</p> <p>17 the levels should be zero because there are synthetic</p> <p>18 methodologies. In layman's terms there are recipes</p> <p>19 to make valsartan without any NDMA, so manufacturers</p> <p>20 should use that recipe. And, you know, that's my</p> <p>21 opinion and I think the levels should be zero for</p> <p>22 NDMA.</p> <p>23 For other genotoxic compounds there are</p> <p>24 specific levels and one has to consult with ICH</p> <p>25 guidelines, ICH M7 for those levels.</p>

<p style="text-align: right;">Page 138</p> <p>1 Q Okay. Well, that's fair. I'll try to</p> <p>2 confine my questions to NDMA and NDEA. Okay?</p> <p>3 A Thank you.</p> <p>4 Q And if I understand your opinion, what</p> <p>5 you've told us is that you're of the opinion that a</p> <p>6 generic formulation that contains NDMA or NDEA is</p> <p>7 not equivalent to Diovan or Exforge, because those</p> <p>8 reference listed drugs have zero NDMA and zero NDEA?</p> <p>9 A The generic drugs that contain NDMA do</p> <p>10 not meet the requirement. I have not tested Diovan</p> <p>11 or I have not tested Exforge. I can only assume</p> <p>12 that they are -- they have zero NDMA because they</p> <p>13 were not recalled, so that's what I said.</p> <p>14 Q Well, yeah, and that's what I wanted</p> <p>15 to get at in terms of trying to understand what we</p> <p>16 have here today.</p> <p>17 The opinion that we framed earlier was -- that</p> <p>18 you intend to offer is that the generic drugs made by</p> <p>19 valsartan-containing medications made by my client</p> <p>20 and some of the other defendants for this litigation,</p> <p>21 you do not believe those drugs are equivalent to the</p> <p>22 reference listed drug, because you have assumed that</p> <p>23 the defendant's generic products contained NDMA and</p> <p>24 NDEA and you assumed that the Diovan and Exforge did</p> <p>25 not?</p>	<p style="text-align: right;">Page 140</p> <p>1 litigation are not equivalent to the reference listed</p> <p>2 drug and you have reached that opinion based on the</p> <p>3 assumption that the reference listed drugs contain</p> <p>4 zero NDMA and zero NDEA, right?</p> <p>5 A Mm-hmm.</p> <p>6 Q Is that "yes"?</p> <p>7 A Yes.</p> <p>8 Q Okay. And one of the things that</p> <p>9 jump-started you in this arena and I presume</p> <p>10 provides you some basis for that assumption is you</p> <p>11 started working with Valisure on nitrosamine testing</p> <p>12 of valsartan before there was even litigation,</p> <p>13 right?</p> <p>14 A So, Clem, as I have stated before, I'm</p> <p>15 not sure when we have actually officially started</p> <p>16 with Valisure. It might have been before, it might</p> <p>17 have been after, but that's what I can tell you.</p> <p>18 Q Fair enough.</p> <p>19 A I'm sure if Daniel would be okay, I</p> <p>20 can, you know, get that information to you.</p> <p>21 Q Fair enough.</p> <p>22 A But the fact remains that whether if</p> <p>23 before or after we tested your client's pills, maybe</p> <p>24 your client's pills, honestly I don't know, I'm not</p> <p>25 prepared to tell you what we have until I can give</p>
<p style="text-align: right;">Page 139</p> <p>1 MR. NIGH: Form objection.</p> <p>2 Q Right?</p> <p>3 A If the manufacturer does not comply</p> <p>4 with the impurity limits which is really zero, they</p> <p>5 are responsible -- and they change their procedure,</p> <p>6 they change their recipe, they change the way they</p> <p>7 make something, then they need to -- there are these</p> <p>8 alerting structures. I'm kind of giving away a lot</p> <p>9 of my opinion that will come later, which is there</p> <p>10 are alerting structures. These are clues for you.</p> <p>11 Those alerting structures were ignored and, hence,</p> <p>12 they now have to deal with NDMA and all the issues</p> <p>13 and --</p> <p>14 Q I appreciate the sneak preview, but I</p> <p>15 honestly don't want to go there. What I just want</p> <p>16 to understand is --</p> <p>17 A The assumption.</p> <p>18 Q Perhaps if you will let me explain, I</p> <p>19 can ask a question that's fair and easy to</p> <p>20 understand, Doctor. I just want to make sure I</p> <p>21 understand the assumption that forms the basis for</p> <p>22 your opinion that you've offered so far in the</p> <p>23 declaration we have.</p> <p>24 You told me that there's two core opinions.</p> <p>25 One of them is that generic drugs at issue in this</p>	<p style="text-align: right;">Page 141</p> <p>1 you reports of those, but they had high, high levels</p> <p>2 of these genotoxic compounds. And I wouldn't want</p> <p>3 anybody to be taking those drugs, you know, on long</p> <p>4 term basis because that would be -- you know, that</p> <p>5 wouldn't be good whether it would be my mother or</p> <p>6 your mother.</p> <p>7 Q Well, my mother already passed, so I'd</p> <p>8 be happy to have her take valsartan with or without</p> <p>9 genotoxic impurities right now.</p> <p>10 A I'm sorry to hear that.</p> <p>11 Q But be that as it may, what I was --</p> <p>12 and I didn't mean to misstate your testimony about</p> <p>13 the timing of your work with Valisure. You did tell</p> <p>14 me you couldn't be sure whether it was before or</p> <p>15 after the FDA involvement, so I grant you that.</p> <p>16 A Yes.</p> <p>17 Q But what you did talk about and what</p> <p>18 you did explain to me was that Valisure brought the</p> <p>19 issue of the potential for nitrosamines in valsartan</p> <p>20 to your attention and sort of asked you to help with</p> <p>21 the testing and evaluation, right?</p> <p>22 A One hundred percent.</p> <p>23 Q Okay. And so you had a chance to look</p> <p>24 at the testing that was done by Valisure early on on</p> <p>25 the valsartan and to independently validate it</p>

<p style="text-align: right;">Page 142</p> <p>1 through the work of your own lab?</p> <p>2 A Yes, we did.</p> <p>3 Q So there is no question in your mind</p> <p>4 that the results of testing as documented by</p> <p>5 Valisure and its findings on nitrosamine contents in</p> <p>6 valsartan were accurate?</p> <p>7 A We repeated Valisure's work according</p> <p>8 to our own procedures and we, I think we -- the</p> <p>9 result what we told Valisure was that the numbers</p> <p>10 they got was pretty much in the ballpark.</p> <p>11 MR. TRISCHLER: Did anyone hear the</p> <p>12 doctors' answer? I saw his lips moving but didn't</p> <p>13 hear anything.</p> <p>14 MR. NIGH: I could hear it.</p> <p>15 A I said. Let me repeat. Can you hear</p> <p>16 me okay?</p> <p>17 Q Now I can.</p> <p>18 A Okay. What I said was we concurred</p> <p>19 with Valisure that they had correct nitrosamine</p> <p>20 numbers for their valsartan pills and they sent to</p> <p>21 us the same pills that they tested. I specifically</p> <p>22 warned Valisure to get it tested at a third-party</p> <p>23 lab. He called me, asked me for my advice. I said</p> <p>24 you want to get it at a third party lab to make</p> <p>25 sure. I think he was planning to do some press</p>	<p style="text-align: right;">Page 144</p> <p>1 minute ago. Bill, do you have it?</p> <p>2 THE VIDEOGRAPHER: I have it. I am</p> <p>3 downloading it. Just give me one moment. For the</p> <p>4 record, that would be Exhibit 28 is the next one in</p> <p>5 line.</p> <p>6 MR. TRISCHLER: Okay. Can you put up</p> <p>7 Exhibit 28, please.</p> <p>8 Q This is on the Valisure letterhead</p> <p>9 dated June 13, 2009.</p> <p>10 A Right.</p> <p>11 Q Take a look at the first couple</p> <p>12 paragraphs. Does it refresh your recollection at</p> <p>13 all?</p> <p>14 A Now I recall. I think they did file</p> <p>15 something with the FDA, but this is regarding DMF, I</p> <p>16 think.</p> <p>17 Q You're correct that it does relate to</p> <p>18 dimethylformamide which is DMF, right?</p> <p>19 A Dimethylformamide.</p> <p>20 Q Formamide, okay? I'll try to do</p> <p>21 better. I didn't do very well in chemistry.</p> <p>22 A No, no. I just get insulted when they</p> <p>23 mispronounce these chemical names, that's all. No</p> <p>24 worries.</p> <p>25 Q I was trying to say the chemical name</p>
<p style="text-align: right;">Page 143</p> <p>1 release or something, and that's what we did. And</p> <p>2 we told them yes, I think, and then he basically did</p> <p>3 something with that data. So...</p> <p>4 Q Okay. And then you mentioned -- and</p> <p>5 so essentially I think you just answered what my</p> <p>6 question was. My question was, did you have the</p> <p>7 opportunity and did in fact independently</p> <p>8 corroborate the Valisure data as it related to</p> <p>9 valsartan nitrosamine quantification?</p> <p>10 A That's correct. We corroborated their</p> <p>11 data.</p> <p>12 Q And then you made mention early on --</p> <p>13 I shouldn't say early on. You paid mention before</p> <p>14 our last break about a citizens petition and you</p> <p>15 suggested that you thought somewhere in your memory</p> <p>16 bank that Valisure might have done a citizens</p> <p>17 petition that might have related some way or somehow</p> <p>18 to valsartan. Do you remember that?</p> <p>19 A Yes. I don't think they have.</p> <p>20 Q I found something I want to ask you</p> <p>21 about, and Frank from my office is there.</p> <p>22 MR. TRISCHLER: Frank, do you have the</p> <p>23 June 13, 2019, Valisure citizens petition and can</p> <p>24 you have that marked as the next numbered exhibit?</p> <p>25 MR. STOY: Yes. I just uploaded it a</p>	<p style="text-align: right;">Page 145</p> <p>1 to distinguish from DMF to refer to drug --</p> <p>2 A Yeah.</p> <p>3 Q So dimethylformamide is subject of</p> <p>4 Exhibit 28, correct?</p> <p>5 A Correct.</p> <p>6 Q But there's also reference to NDEA</p> <p>7 testing was done by Valisure IN this citizens</p> <p>8 petition, correct?</p> <p>9 A Right.</p> <p>10 Q As I said, you saw this citizens</p> <p>11 position before.</p> <p>12 A Right.</p> <p>13 Q And you had validated the test results</p> <p>14 that are reported in here?</p> <p>15 A Yes.</p> <p>16 Q And if we look at Appendix A to the</p> <p>17 report, what we have is a summary of NDMA levels and</p> <p>18 DMF levels in valsartan tested by Valisure and</p> <p>19 confirmed by your lab?</p> <p>20 A Did they mention our name in this</p> <p>21 report, can you Google it?</p> <p>22 Q I don't know, but --</p> <p>23 A If they didn't mention our name, then</p> <p>24 we didn't have anything to do with it.</p> <p>25 Q Well, you already told me that you had</p>

<p style="text-align: right;">Page 146</p> <p>1 validated their testing and corroborated the 2 results, right? 3 A NDMA? 4 Q Right. 5 A NDMA, but that's if they mentioned our 6 name, then it would be corroborated, but if they 7 didn't mention our name, it was on their own. 8 Q Well, I only planned on asking you 9 about the NDMA results reported in this. 10 A Please. 11 Q As you said at least five or six times 12 it's called by Valisure to corroborate their data? 13 A Yes, but you know -- okay. Go ahead. 14 MR. NIGH: Form objection. 15 Q So if you look at the Appendix A, 16 you're looking at the first page there. If you flip 17 to the next page, page 10, there's more results 18 reported. Do you see that? 19 A Right. 20 Q Page 111 there's more results 21 reported? 22 A I don't think we tested that many 23 different pills and lots for them. 24 Q I am only asking about what's shown 25 here in the document. There's more testing</p>	<p style="text-align: right;">Page 148</p> <p>1 MR. TRISCHLER: What's that? 2 MR. NIGH: I just said "form 3 objection." 4 MR. TRISCHLER: I meant what's that to 5 the witness. 6 A And I respond to that I'm not -- I 7 cannot confirm to you that we corroborated it 8 everything that Valisure is presenting in this 9 report vis-a-vis the fact that our name has not been 10 mentioned on this citizen petition. 11 Typically if we do not corroborate something, 12 they shouldn't put our name. If they are not putting 13 our name, it means we didn't have anything to do with 14 these. 15 Q Your assumption that Novartis, Exforge 16 and Diovan formulations contained zero NDMA is not 17 supported in the data from the citizens petition of 18 Valisure, is it? 19 A Based on what Valisure is reporting 20 to, you know, I cannot corroborate their data 21 because we didn't do it. This is their data. 22 Q And their data does not support your 23 assumption. That's all I asked. 24 A If their data is correct -- you know, 25 I don't know if they are data is correct. Now</p>
<p style="text-align: right;">Page 147</p> <p>1 reported, correct? 2 A Okay. 3 Q And the manufacturers whose product 4 was tested was also identified in Appendix A, 5 correct? 6 A Mm-hmm. 7 Q Is that "yes"? 8 A Yes. 9 Q Interestingly, one of the 10 manufacturers is Novartis. 11 A Okay. 12 Q And if you look at page 12, there is 13 results of seven test samples of Novartis product 14 listed, correct? 15 A Right. 16 Q There was NDMA found in every single 17 Novartis tablet, correct? 18 A Yes. 19 Q Is that correct? 20 A That's what you're showing me. 21 Q So your assumption that underlies your 22 opinion in this case that Novartis' valsartan 23 contained zero NDMA is not supported in the testing 24 done by Valisure and it was validated by your lab. 25 MR. NIGH: Form objection.</p>	<p style="text-align: right;">Page 149</p> <p>1 having said that, you know, Clem, the levels that 2 were -- the interim allowable limit of NDMA, as you 3 know, is 96 nanograms. So under the recall, 4 official recall and notice, anything under 96 5 nanograms would not be recalled. So Novartis would 6 not be a recalled product. 7 Q I didn't ask you if it would be a 8 recalled product and you were also very clear to me, 9 Doctor, that NDMA and NDEA content in its drug 10 product must be zero. You said that five times to 11 me. 12 A That should be the goal of the 13 manufacturers to have zero NDMA and NDEA. 14 Q And you criticized my clients because 15 they had NDMA and NDEA levels higher than zero. 16 A They had levels of 2,000 and 3,000 17 nanograms. 18 MR. NIGH: Hold on. Hold on. Hold 19 on. Hold on. Form objection. Does he even know 20 your client? 21 MR. TRISCHLER: He's your expert. I 22 don't know. 23 MR. NIGH: Okay, because we are 24 getting way off comment on some of these topics. He 25 has not said in terms of your client.</p>

<p style="text-align: right;">Page 150</p> <p>1 MR. TRISCHLER: He just said my 2 client. 3 Q Dose levels of 2,000 nanograms; is 4 that your testimony, sir? 5 A I don't -- I am going on what was 6 published by FDA. So you can Google that and see 7 what FDA was published and double check that to see 8 if your clients is part of that FDA recall and FDA 9 numbers. 10 Q I can do a lot of things, Doctor. I 11 spend way too much time online. What I'd like to do 12 is ask you questions. And my question is, is it 13 your testimony that Mylan had NDEA reported at 14 levels of 2,000 to 3,000 nanograms in its 15 valsartan-containing products? 16 MR. NIGH: This is far outside the 17 scope of his certification and declaration at this 18 point. I mean, you can read it. He doesn't mention 19 a single thing about Mylan. 20 MR. TRISCHLER: He volunteered and I 21 am allowed to follow that up. 22 MR. NIGH: No, that's not actually 23 true. I have a lot of questions to go far outside 24 the scope at this point, but this is way outside of 25 the scope of his seven page declaration. Not a</p>	<p style="text-align: right;">Page 152</p> <p>1 products contain any NDMA, NDEA is not equivalent to 2 Novartis who is the reference listed drug holder, 3 because Novartis' levels are zero. The data from 4 Valisure suggests that that's not true. Agreed? 5 A My position is that levels of NDMA and 6 NDEA should be zero in any valsartan pills. 7 Novartis might have some valsartan at higher level, 8 have some NDMA in it. They might have had -- in 9 fact, they were buying -- from my understanding they 10 were buying ZHP's API and they were using ZHP's API, 11 so I am not surprised they ended up with some NDMA, 12 but prior to ZHP and any of the defendants' products 13 Diovan and, you know, Exforge going generic, I 14 believe they had their procedure, their process 15 produced no NDMA. 16 Q Have you ever reviewed the new drug 17 application for Diovan? 18 A I have reviewed a lot of documents, 19 yes. 20 Q I didn't ask if you reviewed a lot of 21 documents. Have you ever reviewed the new drug 22 application for Diovan? 23 A I have reviewed it. 24 Q Where did you get it? 25 A You know, I think maybe, you know, the</p>
<p style="text-align: right;">Page 151</p> <p>1 single place in here does he ever mention any of the 2 defendants' testing levels and I think you know 3 that. So, again, at this point we're getting way 4 outside. I have allowed some exploration at some 5 point, but this has no basis in his declaration at 6 this point. 7 MR. TRISCHLER: I think I'm entitled 8 to an answer to the question. You've objected. You 9 can argue whether -- 10 MR. NIGH: I am going to instruct him 11 not to answer at this point. We have gone far 12 outside the scope. 13 MR. TRISCHLER: Just so that I'm 14 clear, the witness stated that my client had levels 15 of 2,000 to 3,000 nanograms and you are not allowing 16 me to follow up on that? 17 MR. NIGH: Just so you're clear, I 18 think that question was far outside the scope in the 19 first place. He is not here to offer an opinion as 20 to what the levels are or your client's levels. He 21 is not here to offer an opinion as to what any of 22 the clients' levels are. His opinion clearly states 23 valsartan which contaminated NDMA or NDEA, period, 24 not about levels. 25 Q You told us, Doctor, generic drug</p>	<p style="text-align: right;">Page 153</p> <p>1 plaintiff's lawyer shared it with me. 2 Q I'm surprised that Novartis would turn 3 over their proprietary documents to the plaintiff's 4 lawyers. So your testimony is you've seen the new 5 drug application? 6 A I might have seen it. I reviewed a 7 lot of different documents. 8 Q Well, it was not disclosed or provided 9 in any of the materials that were given here to me. 10 A I cannot recall, but I reviewed a lot 11 of different documents relating to valsartan 12 manufacturing; valsartan -- you know, there is a lot 13 of public information regarding the manufacturing 14 process. 15 Q Chemistry manufacturing controls 16 submissions as part of Novartis' new drug 17 application. It's not public information, is it? 18 A What is your question? 19 Q I just asked you that one. There is a 20 CMC section a new drug application, public 21 information. 22 A What is your question? 23 Q I will ask it a third time. Is the 24 CMC section of a new drug application public 25 information?</p>

<p style="text-align: right;">Page 154</p> <p>1 A CMC section shouldn't be public</p> <p>2 information.</p> <p>3 Q So I am trying to understand your</p> <p>4 testimony under oath that you've seen and been</p> <p>5 provided with the NDA for Diovan. Where did you get</p> <p>6 it?</p> <p>7 A I said I have reviewed. I didn't say</p> <p>8 I've seen it. I said I have reviewed a lot of</p> <p>9 documents, you know, from different manufacturers,</p> <p>10 perhaps including Novartis' procedures, but</p> <p>11 Novartis' procedures and chemical manufacturing</p> <p>12 procedures has been disclosed in their patents.</p> <p>13 It's been published. There's plenty of literature</p> <p>14 on it.</p> <p>15 Q So if I hear what you're saying now</p> <p>16 and if we're looking for honest, forthright</p> <p>17 testimony, it sounds like you don't know whether</p> <p>18 you've seen the NDA for Diovan, correct?</p> <p>19 MR. NIGH: Form objection.</p> <p>20 A I don't know if I've seen it.</p> <p>21 Q All right. In your career, sir, have</p> <p>22 you ever prepared an abbreviated new drug</p> <p>23 application seeking to obtain FDA approval to market</p> <p>24 any generic equivalent drug product?</p> <p>25 A In my career I have been involved in</p>	<p style="text-align: right;">Page 156</p> <p>1 A I know.</p> <p>2 Q Sitting here today providing -- let me</p> <p>3 finish before you start.</p> <p>4 Sitting here today providing testimony under</p> <p>5 oath, you can't name one drug product where you were</p> <p>6 involved in submitting the abbreviated new drug</p> <p>7 applications for its generic formulation, right?</p> <p>8 A I cannot recall.</p> <p>9 Q Have you ever worked in regulatory</p> <p>10 affairs for a generic drug manufacturer?</p> <p>11 A No.</p> <p>12 Q Have you ever --</p> <p>13 A I have not worked in regulatory</p> <p>14 affairs for any generic manufacturers.</p> <p>15 Q Have you ever worked or been employed</p> <p>16 by the FDA?</p> <p>17 A I have never been employed by the FDA.</p> <p>18 Q Have you ever -- are you familiar with</p> <p>19 the Center for Drug Evaluation and Research, CDER?</p> <p>20 A I have attended many meetings at CDER.</p> <p>21 Q Have you ever worked with CDER where</p> <p>22 you've had responsibility for evaluating new drug or</p> <p>23 new drug applications?</p> <p>24 A I have not been involved with CDER.</p> <p>25 You should restate your question.</p>
<p style="text-align: right;">Page 155</p> <p>1 many IND filings, CMC sections of IND, CMC sections</p> <p>2 of NDA, ANDA for my clients, not specifically for</p> <p>3 any of my own specific products.</p> <p>4 Q My question was have you ever been</p> <p>5 involved in preparing --</p> <p>6 A Yes, I have.</p> <p>7 MR. NIGH: Hold on. Dr. Najafi. Wait</p> <p>8 until he finishes his question.</p> <p>9 A Sorry.</p> <p>10 MR. NIGH: And then answer. We're</p> <p>11 getting --</p> <p>12 MR. TRISCHLER: Sorry, Dan.</p> <p>13 Q What abbreviated drug applications did</p> <p>14 you prepare and submit to the FDA?</p> <p>15 A Confidential.</p> <p>16 Q For what drugs?</p> <p>17 A For drugs that -- from our clients'</p> <p>18 drugs.</p> <p>19 Q Tell me the names of the drugs. The</p> <p>20 active pharmaceutical ingredients are not</p> <p>21 confidential.</p> <p>22 A I can not recall right now. Also,</p> <p>23 it's client-specific and a lot of our clients don't</p> <p>24 want to have their names disclosed.</p> <p>25 Q I haven't asked your client's names.</p>	<p style="text-align: right;">Page 157</p> <p>1 Q I should or you need me to?</p> <p>2 A Please restate your question.</p> <p>3 Q Have you ever worked with CDER where</p> <p>4 you had responsibility for evaluating new drug or</p> <p>5 abbreviated new drug applications?</p> <p>6 A I have not worked with CDER in</p> <p>7 evaluating any new drug application.</p> <p>8 Q Have you ever been retained as a</p> <p>9 consultant by FDA office of generic drugs to assist</p> <p>10 in evaluating any portion of an abbreviated new drug</p> <p>11 application?</p> <p>12 A I have not been involved in generic</p> <p>13 drug division of the FDA.</p> <p>14 Q And I think it's Section 4 of your</p> <p>15 report -- your declaration you describe FDA</p> <p>16 expectations and requirements for generic drug</p> <p>17 manufacturers. Do you recall that?</p> <p>18 A Could you show it to me?</p> <p>19 Q Sure.</p> <p>20 A Put it on the screen.</p> <p>21 MR. TRISCHLER: It's Exhibit 1. Can</p> <p>22 you put it up, please.</p> <p>23 A Highlight it.</p> <p>24 Q Can you flip through it? I think it's</p> <p>25 section 4. I think it starts on page 5, maybe, if I</p>

<p style="text-align: right;">Page 158</p> <p>1 recall correctly. There we go. Do you see that?</p> <p>2 A Yes.</p> <p>3 Q And as I was saying, this is the</p> <p>4 section of your report where I think you proceed to</p> <p>5 describe what you consider to be the expectations or</p> <p>6 some of the expectations and requirements for a</p> <p>7 generic drug manufacturer, right?</p> <p>8 A Mm-hmm.</p> <p>9 Q Is that "yes"?</p> <p>10 A Yes.</p> <p>11 Q The fact of the matter is, though,</p> <p>12 Doctor, that you're never had personal</p> <p>13 responsibility for synthesizing API that was used</p> <p>14 for generic drug formulation, correct?</p> <p>15 A I have not had responsibility in</p> <p>16 synthesizing an API for a generic drug manufacturer,</p> <p>17 but I have been involved in, you know, drug</p> <p>18 development and I've been involved with lots of</p> <p>19 FDA-related activities and the spirit of what I have</p> <p>20 put in is if and when you change the chemical</p> <p>21 process, if you make lasagna by following step one,</p> <p>22 step two, step three, and if you change that and you</p> <p>23 create your own recipe, you have responsibility to</p> <p>24 do proper due diligence to look at structural</p> <p>25 molecules that give you structural clue to</p>	<p style="text-align: right;">Page 160</p> <p>1 file in connection with an API for a generic drug?</p> <p>2 A Not personally.</p> <p>3 Q In the notes of deposition that</p> <p>4 brought us here today, I asked you to provide</p> <p>5 certain materials to me at the time of the</p> <p>6 deposition. One of the things I asked for were any</p> <p>7 and all papers that you prepared on the topic of</p> <p>8 drug safety and cancer risk. Do you remember seeing</p> <p>9 that request in the notice?</p> <p>10 A Yes, I have.</p> <p>11 Q I did not receive any papers or</p> <p>12 publications on those topics, so I have to assume</p> <p>13 that you have never published on those issues.</p> <p>14 Would that be a fair assumption on my part?</p> <p>15 A I have not published on anything, any</p> <p>16 genotoxic compound, nitrosamines except the citizen</p> <p>17 petition which we filed with the FDA regarding</p> <p>18 nitrosamine which FDA corroborated 100 percent, and</p> <p>19 I've also presented at a generic manufacturing</p> <p>20 symposium where my audience was a whole huge number</p> <p>21 of generic manufacturing people.</p> <p>22 Q I appreciate that, but my question was</p> <p>23 a little broader than that. I had asked for all</p> <p>24 papers and publications prepared on the broader</p> <p>25 topic of drug safety and cancer risk. Have you ever</p>
<p style="text-align: right;">Page 159</p> <p>1 protection problem and you need to disclose that to</p> <p>2 the FDA and you need to do proper due diligence and</p> <p>3 effectively look for those, you know, potential</p> <p>4 problem and look for genotoxic compounds and report</p> <p>5 it.</p> <p>6 Q Have you ever developed a synthetic</p> <p>7 process used for the API of a generic drug</p> <p>8 formulation?</p> <p>9 A I have developed synthetic process of</p> <p>10 hundreds of molecules in my time and I continue to</p> <p>11 develop processes for hundreds of molecules, but not</p> <p>12 for a generic drug, but I can assure you I</p> <p>13 understand the synthesis synthetic procedure of</p> <p>14 valsartan.</p> <p>15 Q Have you ever had oversight</p> <p>16 responsibility for manufacturing a generic drug</p> <p>17 product?</p> <p>18 A No. I have not had oversight</p> <p>19 responsibilities for a synthesis of a generic drug</p> <p>20 product or drug substance, but I've had</p> <p>21 manufacturing responsibilities for lots of synthetic</p> <p>22 molecules in large scale at my previous company,</p> <p>23 Aldridge Chemical, at Rhone-Poulence</p> <p>24 Pharmaceuticals, et cetera, and NovaBay.</p> <p>25 Q Have you ever prepared a drug master</p>	<p style="text-align: right;">Page 161</p> <p>1 published on those topics?</p> <p>2 A I haven't published on those topics</p> <p>3 and what I can -- you know, there are lot of</p> <p>4 publications. That's really a toxicologist and</p> <p>5 epidemiologist sort of activity. I rely on them.</p> <p>6 Q And what you were answering on the</p> <p>7 topic of nitrosamines what you told me is that</p> <p>8 you've not submitted any peer-reviewed publications</p> <p>9 on the issue of nitrosamines and drug products,</p> <p>10 correct?</p> <p>11 A So what's your definition of peer</p> <p>12 reviewed?</p> <p>13 Q My definition of peer review would be</p> <p>14 a publication in a scientific journal that is</p> <p>15 reviewed by scientists in the field for accuracy,</p> <p>16 quality and reliability of methods prior to the time</p> <p>17 that it's published.</p> <p>18 A Our citizen physician, my citizen</p> <p>19 petition for ranitidine Zantac meets those</p> <p>20 criterias, so under that circumstance it is peer</p> <p>21 reviewed.</p> <p>22 Q So you consider a citizens petition to</p> <p>23 be a peer-reviewed publication?</p> <p>24 A Absolutely.</p> <p>25 Q Who can submit a citizens petition?</p>

<p style="text-align: right;">Page 162</p> <p>1 A Anybody can submit a citizen petition.</p> <p>2 Q If I sent a citizens petition saying</p> <p>3 Dr. Najafi's declaration in this case is unreliable,</p> <p>4 has that been peer reviewed?</p> <p>5 A You can certainly do that and it will</p> <p>6 be peer reviewed by FDA scientists and they will</p> <p>7 then respond to you that Clem, you're wrong.</p> <p>8 Q In formulating the opinions that are</p> <p>9 contained in this declaration that we're looking at</p> <p>10 now, did you review any internal Mylan documents?</p> <p>11 A In formulating this last declaration,</p> <p>12 I don't believe so.</p> <p>13 Q Did you review by ZHP documents?</p> <p>14 A I have reviewed both Mylan and ZHP</p> <p>15 documents months ago but not in formulating this</p> <p>16 declaration.</p> <p>17 Q And if I ask the same question for the</p> <p>18 other manufacturer defendants to this litigation:</p> <p>19 Teva, Aurobindo, Hetero, Torrent; have you reviewed</p> <p>20 any of their documents?</p> <p>21 A I have reviewed. I've spent hours and</p> <p>22 hours looking at their manufacturing issues, looking</p> <p>23 at their, you know, all of that, but not for this,</p> <p>24 you know, putting this declaration together.</p> <p>25 Q So in terms of those two core opinions</p>	<p style="text-align: right;">Page 164</p> <p>1 (A recess was taken.)</p> <p>2 (After the recess the following</p> <p>3 occurred:)</p> <p>4 THE VIDEOGRAPHER: The time is now</p> <p>5 2:48. This begins Media unit 5. You may proceed.</p> <p>6 BY MR. TRISCHLER:</p> <p>7 Q Doctor, I just have a few other things</p> <p>8 I want to cover with you. One of the documents that</p> <p>9 was in your file that I was provided with was a</p> <p>10 chart entitled "valsartan products not currently</p> <p>11 recalled." Are you familiar with that chart?</p> <p>12 A Would you bring it up so we can be</p> <p>13 looking at the same thing?</p> <p>14 Q Sure.</p> <p>15 MR. TRISCHLER: Frank, are you able</p> <p>16 to -- it was not in the group of exhibits that I</p> <p>17 premarked. Are you able to pull it up, Frank, and</p> <p>18 get it in front of the witness?</p> <p>19 MR. STOY: Yes. Let me try to find it</p> <p>20 here. I am going to attempt to share my screen. Is</p> <p>21 this the document?</p> <p>22 MR. TRISCHLER: Yes, that's it. Thank</p> <p>23 you, Frank. I guess we will have this marked as an</p> <p>24 exhibit and sent to the reporter through the chart,</p> <p>25 but whatever the next numbered exhibit is.</p>
<p style="text-align: right;">Page 163</p> <p>1 we talked about, you don't plan to -- you're not</p> <p>2 relying upon and did not consider any of the -- any</p> <p>3 internal documents from any of the manufacturers?</p> <p>4 A I did not, no.</p> <p>5 Q I asked you before if you reviewed the</p> <p>6 new drug application for Diovan and you said you</p> <p>7 could not. Just for completeness sake, do you know</p> <p>8 if you ever reviewed the new drug application for</p> <p>9 Exforge or Exforge HCT?</p> <p>10 A I cannot recall. I believe I've</p> <p>11 reviewed a lot of the defendants' material. I might</p> <p>12 have reviewed some of the publicly available</p> <p>13 information on the work Ciba-Geigy did which led to</p> <p>14 Diovan.</p> <p>15 I've looked at their patents. I've looked at</p> <p>16 their procedures, their recipes, their synthesis,</p> <p>17 published data, a lot of that. I have looked at a</p> <p>18 lot of documents over the last year and a half or so.</p> <p>19 MR. TRISCHLER: Let's take a break,</p> <p>20 please. I want to look at some notes and see what I</p> <p>21 want to do next.</p> <p>22 MR. NIGH: Take a ten minute break?</p> <p>23 MR. TRISCHLER: Sure.</p> <p>24 THE VIDEOGRAPHER: The time is 2:22.</p> <p>25 This concludes Media No. 4.</p>	<p style="text-align: right;">Page 165</p> <p>1 THE VIDEOGRAPHER: That will be 29.</p> <p>2 MR. TRISCHLER: Thank you.</p> <p>3 BY MR. TRISCHLER:</p> <p>4 Q Doctor, can you see this Exhibit 29?</p> <p>5 A It is very tiny. Yes, I do.</p> <p>6 Q It's a 15 page document. At the top</p> <p>7 it says "valsartan products not currently recalled"</p> <p>8 dated September 21, 2015, and it was provided to me</p> <p>9 by your counsel as part of your file. Do you recall</p> <p>10 that?</p> <p>11 A Yes.</p> <p>12 Q And if I understand correctly this</p> <p>13 would be a list of valsartan products, marketed and</p> <p>14 sold in the United States that were not subject to</p> <p>15 any recall at least as of September 2018, right?</p> <p>16 A I believe so.</p> <p>17 Q And you had mentioned earlier that</p> <p>18 under the valsartan recalls, products were recalled</p> <p>19 if they had NDMA content above 96 nanograms per</p> <p>20 milliliter, right?</p> <p>21 MR. NIGH: Objection. Go ahead.</p> <p>22 Q You can answer.</p> <p>23 A Ninety-six nanograms dosage you end up</p> <p>24 consuming per day.</p> <p>25 Q The limit for NDEA, there was a</p>

<p style="text-align: right;">Page 166</p> <p>1 separate limit for NDEA, right?</p> <p>2 A I think NDEA was far lower, maybe 12</p> <p>3 or 20, something like that.</p> <p>4 Q Does 26.5 sound right?</p> <p>5 A Yes.</p> <p>6 Q And so if valsartan products were</p> <p>7 tested and the limits observed were above those</p> <p>8 levels of 96 nanograms for NDMA and 26.5 nanograms</p> <p>9 for NDEA, they were recalled, is that your</p> <p>10 understanding?</p> <p>11 A That's my understanding.</p> <p>12 Q And so this list would be a list of</p> <p>13 products that had NDEA content of either zero or</p> <p>14 less than 96 or somewhere in between?</p> <p>15 A Right.</p> <p>16 Q And these would be -- this list that</p> <p>17 we will mark as Exhibit 29 is a list of product that</p> <p>18 would have been tested and had NDEA content of</p> <p>19 either zero or 26.5 or something in between.</p> <p>20 A Right.</p> <p>21 Q To your knowledge, have you</p> <p>22 independently tested any of these</p> <p>23 valsartan-containing medications that appear on this</p> <p>24 Exhibit 29?</p> <p>25 A I have not. I'm not prepared in this</p>	<p style="text-align: right;">Page 168</p> <p>1 should be allowed in any valsartan product, period.</p> <p>2 Zero. So if they contain NDMA and NDEA and FDA is</p> <p>3 allowing it above certain limit, that's FDA's</p> <p>4 prerogative, but in my expert opinion, no NDMA or</p> <p>5 NDEA should be allowed.</p> <p>6 I am not a toxicologist, but I know something</p> <p>7 about the chemistry of NDMA and the fact that it</p> <p>8 comes a methylating agent, and methylating agents are</p> <p>9 a fantastic cancer causing agent.</p> <p>10 MR. NIGH: Dr. Najafi, make sure you</p> <p>11 let him finish his question before you answer.</p> <p>12 THE WITNESS: My apologies.</p> <p>13 Q The limits established by FDA that</p> <p>14 you've referenced --</p> <p>15 A Right.</p> <p>16 Q -- 96 nanograms per millimeter for</p> <p>17 NDMA, that limit remains in effect to this day, does</p> <p>18 it not?</p> <p>19 MR. NIGH: Object to form.</p> <p>20 A As far as I know, FDA currently is</p> <p>21 accepting 96 nanograms as an interim sort of level,</p> <p>22 but their goal is going to be zero and their goal is</p> <p>23 going to be basically FDA -- I'm reading from FDA's</p> <p>24 guidance. It says FDA advises that nitrosamines</p> <p>25 should be absent, not detectable for ARBs, API or</p>
<p style="text-align: right;">Page 167</p> <p>1 meeting to to take a look at these and compare it</p> <p>2 with what we have or have not listed, because I'm</p> <p>3 just -- I don't have the documentations in front of</p> <p>4 me to tell you what got tested and what didn't.</p> <p>5 Q Okay, but based on what we know right</p> <p>6 now, all of the drug products listed on Exhibit 29</p> <p>7 may very well have had some NDMA or NDEA in the</p> <p>8 product, it was simply below the limit established</p> <p>9 by FDA?</p> <p>10 A That's what FDA has obviously done.</p> <p>11 They have made those determinations based on this</p> <p>12 interim level, interim level which is 96 or</p> <p>13 20-something nanograms of NDEA.</p> <p>14 Q So as far as we know, every drug</p> <p>15 listed on Exhibit 29 had some NDMA or NDEA in it,</p> <p>16 right?</p> <p>17 A As far as I can tell you, I have no</p> <p>18 knowledge of what the exact numbers of NDMA or NDEA</p> <p>19 is in any of these products. All I can attest to is</p> <p>20 that they were not recalled by the FDA.</p> <p>21 Q And so you cannot rule out the</p> <p>22 possibility that every drug listed on Exhibit 29 had</p> <p>23 some NDMA or NDEA?</p> <p>24 A I cannot rule out. Let me just</p> <p>25 restate my position. I believe no NDMA or NDEA</p>	<p style="text-align: right;">Page 169</p> <p>1 ARB product period, stop. It's been cited in my FDA</p> <p>2 general advice document which is actually cited in</p> <p>3 my report.</p> <p>4 Q All I asked you was that the limit of</p> <p>5 permissible NDMA content of 96 nanograms per</p> <p>6 milliliter remains in effect to this day.</p> <p>7 A As far as I know, 96 nanograms remains</p> <p>8 in effect and is acceptable today, but may not be</p> <p>9 acceptable tomorrow.</p> <p>10 Q And the 26.5 nanograms limit for NDEA</p> <p>11 remains in effect to this day?</p> <p>12 A As far as I can tell, that remains as</p> <p>13 an interim acceptable level today but, again, their</p> <p>14 guidance says they are going to go to zero. So I am</p> <p>15 answering your question.</p> <p>16 MR. TRISCHLER: All right. I have no</p> <p>17 further questions of the witness at this time. I do</p> <p>18 think that there are documents that we have</p> <p>19 requested that have been -- excuse me, documents</p> <p>20 that have been identified worked on by this witness</p> <p>21 that were identified during the course of this</p> <p>22 deposition that are relevant to the witness that</p> <p>23 have been disclosed in this case and that the</p> <p>24 witness has been offered.</p> <p>25 I am going to reserve the right to</p>

<p style="text-align: right;">Page 170</p> <p>1 bring a motion on that issue to obtain those</p> <p>2 documents and those records and to redepose the</p> <p>3 witness on those issues, but for now I don't have</p> <p>4 any further questions, although I believe there may</p> <p>5 be a few other people on my side that have some</p> <p>6 followup.</p> <p>7 MR. NIGH: Mr. Trischler, I am going</p> <p>8 to put my position briefly. I think at this point</p> <p>9 we've gone over four hours of record time which is,</p> <p>10 in many of these questions, have been far outside of</p> <p>11 the scope. And the vast majority of documents, if</p> <p>12 there are any, we presented those objections 48</p> <p>13 hours ago and do not believe there is a basis to</p> <p>14 come back for this deposition.</p> <p>15 In addition, I'm surprised that it's</p> <p>16 even gone four hours, but it sounds like it's going</p> <p>17 to go even further and so I don't even know if there</p> <p>18 will be any time at the end of this. And to the</p> <p>19 extent that there is an argument being raised of</p> <p>20 missing documents, really, the timing here has just</p> <p>21 gone far longer than we think was necessary. That's</p> <p>22 my position.</p> <p>23 CROSS-EXAMINATION</p> <p>24 BY MR. GISLESON:</p> <p>25 Q Good afternoon, Doctor. My name is</p>	<p style="text-align: right;">Page 172</p> <p>1 FDA utilizes USP monographs?</p> <p>2 A Can you be specific? You know, what</p> <p>3 do you mean by to what extent FDA utilizes?</p> <p>4 Q Do you have an understanding as to how</p> <p>5 FDA utilizes USP monographs?</p> <p>6 MR. NIGH: Objection. Form.</p> <p>7 A USP primarily works with the sponsor</p> <p>8 of the innovators to get the -- you know, basically</p> <p>9 to get the drug, the generic drugs, you know,</p> <p>10 effectively easing the generic drug availability.</p> <p>11 So, for example USP toward the end of the drug</p> <p>12 patent, USP contacts the brand and says "share with</p> <p>13 me your protocol. Share with me your standard.</p> <p>14 Share with me your impurities," and the drug -- the</p> <p>15 brand usually does that. If they don't do it, USP</p> <p>16 develops its own standards and then everybody has to</p> <p>17 meet that minimum standard.</p> <p>18 Q In your experience, are the USP</p> <p>19 standards reliable for manufacturers?</p> <p>20 MR. NIGH: Form objection.</p> <p>21 A Could you repeat your question?</p> <p>22 Q Sure. In your experience, are USP</p> <p>23 monographs accurate in their prescription of the</p> <p>24 drug products addressed in the monographs?</p> <p>25 MR. NIGH: Form objection.</p>
<p style="text-align: right;">Page 171</p> <p>1 John Gisleson and I represent Aurobindo.</p> <p>2 MR. GISLESON: If we could go back</p> <p>3 please, Bill, and pull up Exhibit 17, which is the</p> <p>4 valsartan USP monograph.</p> <p>5 Q So, Doctor, in your career to what</p> <p>6 extent have you utilized USP monographs in your</p> <p>7 work?</p> <p>8 A We use it almost every day, every week</p> <p>9 at Emery Pharma to effectively follow, you know, and</p> <p>10 release drug product and drug substance at Emery.</p> <p>11 Q To your knowledge are the USP</p> <p>12 monographs utilized in connection with</p> <p>13 manufacturing?</p> <p>14 A USP monographs are utilized in</p> <p>15 connection with manufacturing, yes.</p> <p>16 Q Do you know whether the FDA relies at</p> <p>17 all on USP monographs?</p> <p>18 A To some extent they do. FDA and USP</p> <p>19 have sort of a tangential relationship with the USP.</p> <p>20 USP is an independent company and it was formed 200</p> <p>21 years ago for the purpose of, essentially,</p> <p>22 standardizing our drug supplies and trying to</p> <p>23 develop a standardized quality system for the drug</p> <p>24 on the market.</p> <p>25 Q Do you have an understanding as to how</p>	<p style="text-align: right;">Page 173</p> <p>1 A In terms of reliability, it's a</p> <p>2 minimum standard that you have to meet, but we often</p> <p>3 go above and beyond USP.</p> <p>4 Q And in your experience, are the USP</p> <p>5 monographs reliable in terms of the accuracy of the</p> <p>6 information that they contain?</p> <p>7 MR. NIGH: Objection.</p> <p>8 A In my experience, USP monograph is the</p> <p>9 starting point for, you know, for basically looking</p> <p>10 at the impurity profile.</p> <p>11 Q And if we look at Exhibit 17, does</p> <p>12 this identify specific impurities that have been</p> <p>13 found in the valsartan product?</p> <p>14 A They do.</p> <p>15 Q What are the specific impurities that</p> <p>16 are identified there?</p> <p>17 A There are a couple of impurities</p> <p>18 listed; impurity A, impurity B, but in fact there</p> <p>19 are more impurities.</p> <p>20 Q Do you have an understanding why,</p> <p>21 then, the USP monograph didn't identify all</p> <p>22 impurities?</p> <p>23 MR. NIGH: Form objection.</p> <p>24 A We often find other impurities and we</p> <p>25 bring it to the attention of the sponsor and show</p>

<p style="text-align: right;">Page 174</p> <p>1 them that these impurities need to be identified or</p> <p>2 if the levels are -- meet certain standards, they</p> <p>3 need to be identified or they need to be, you know,</p> <p>4 purified, tested, quantified. Really, there are</p> <p>5 different standards, but no, USP -- how can I say</p> <p>6 it, it's really just -- it's really an entry point,</p> <p>7 you know. It's really a starting point. It's a</p> <p>8 guidance.</p> <p>9 Q In your experience are USP monographs</p> <p>10 updated from time to time?</p> <p>11 A I believe they are.</p> <p>12 Q In your experience, when USP</p> <p>13 monographs are updated, would they also include</p> <p>14 additional impurities that weren't previously known?</p> <p>15 A They often do, but they are very slow</p> <p>16 in doing that. A company such as ours would</p> <p>17 actually need to contact USP and say, hey, we</p> <p>18 actually found additional impurities, you know, you</p> <p>19 should list that and it might take them a couple of</p> <p>20 years to bring that up and do their own testing and</p> <p>21 corroborate and all of that and then it might get</p> <p>22 into that, you know it might get into sort of USP</p> <p>23 monograph.</p> <p>24 Q And in your experience it's good</p> <p>25 practice when new impurities are identified to</p>	<p style="text-align: right;">Page 176</p> <p>1 impurity profile, they are using chromatographic</p> <p>2 technique. Chromatographic technique means --</p> <p>3 meaning in this case high pressure liquid</p> <p>4 chromatography and that's it.</p> <p>5 Q If we look under the impurities</p> <p>6 section on this first page, there's a reference to</p> <p>7 chromatographic system, see chromatography 621</p> <p>8 system suitability and then it has mode LC detector</p> <p>9 UV 230 NM.</p> <p>10 So what is the information that provides to a</p> <p>11 manufacturer as to how to test for an impurity?</p> <p>12 A You're getting fairly technical here.</p> <p>13 I don't know whether this is useful for this</p> <p>14 conversation, but the HPLC is an instrument that</p> <p>15 there are pumps attached to it. The pumps are</p> <p>16 pushing. There are two pumps pushing some vents</p> <p>17 into a column. There's solvent A, solvent B, and</p> <p>18 depending on what's in the solvent A and B, the</p> <p>19 column gets conditioned so that the column is a</p> <p>20 stationary phase. And so the separation happens</p> <p>21 through the HPLC column and then it goes through a</p> <p>22 detector and then that detector would be, you know,</p> <p>23 UV detector. It could be, you know, CHAD detector</p> <p>24 which stands for charge aerosol detector. It could</p> <p>25 be ELT detector. It could be a mass spec detector.</p>
<p style="text-align: right;">Page 175</p> <p>1 report those impurities to the FDA; is that right?</p> <p>2 A Absolutely. Reporting them to USP is</p> <p>3 a good practice. If it's a genotoxic compound, I</p> <p>4 think you want to make an more urgent case reporting</p> <p>5 it to the manufacturer, reporting it to the USP,</p> <p>6 reporting it to the FDA in the case of, for example,</p> <p>7 sartans or ranitidine, Zantac and others.</p> <p>8 Q Does the -- and we'll look at</p> <p>9 Exhibit 17 specifically. Does this USP monograph</p> <p>10 identify how to test for impurities?</p> <p>11 A This USP monograph does provide you</p> <p>12 with a basic methodology to identify some of the</p> <p>13 impurities.</p> <p>14 Q What is the methodology that's</p> <p>15 identified on this USP monograph?</p> <p>16 A Thank on hang on a second. There</p> <p>17 is -- to identify impurities you have to go through</p> <p>18 set up either HPLC or gas chromatography, various</p> <p>19 instrumentation and set it up, set up the instrument</p> <p>20 and run it according to the basic principle that USP</p> <p>21 lays down.</p> <p>22 Q What are the specific tests or tests</p> <p>23 that are identified in this USP monograph for</p> <p>24 testing for the presence of impurities?</p> <p>25 A So they use -- basically to assess</p>	<p style="text-align: right;">Page 177</p> <p>1 So it goes through the detector and comes out</p> <p>2 and out of that detector. So any UV active compound</p> <p>3 gets detected. So in this case they are looking at</p> <p>4 for UV active compound.</p> <p>5 Q How much -- I'm sorry. Continue. Are</p> <p>6 nitrosamines UV active compounds?</p> <p>7 A Nitrosamines are not UV active</p> <p>8 compounds. So they become invisible, so UV.</p> <p>9 Q Using the chromatographic system with</p> <p>10 liquid chromatography and a UV detector, in your</p> <p>11 experience is that capable of identifying</p> <p>12 nitrosamines?</p> <p>13 A In my experience you have detectors</p> <p>14 are not capable of detecting nitrosamines.</p> <p>15 Q Does this USP monograph identify that</p> <p>16 a manufacturer should use gas chromatography, mass</p> <p>17 spectrometry to test for the presence of nitrosamine</p> <p>18 impurities?</p> <p>19 MR. NIGH: Form objection.</p> <p>20 A So this specific monograph does not</p> <p>21 provide you with the, you know, HPLC mass spec</p> <p>22 detector detection.</p> <p>23 However, you know, the chemist and the</p> <p>24 synthetic chemist who is involved with the synthesis</p> <p>25 of the drug should consider, you know, methods that</p>

<p style="text-align: right;">Page 178</p> <p>1 do not -- that can potentially show the none UV</p> <p>2 active compound such as nitrosamine and use of mass</p> <p>3 spec. For example, HPLC connected to a mass spec or</p> <p>4 GC connected to a mass spec, that's been around since</p> <p>5 I was an undergraduate in 1979.</p> <p>6 Q How many to your knowledge -- strike</p> <p>7 that.</p> <p>8 What drugs prior to June 2018 were found to</p> <p>9 contain nitrosamine impurities?</p> <p>10 MR. NIGH: Form objection.</p> <p>11 A To my knowledge, you know, the drugs</p> <p>12 that contained nitrosamine impurities, perhaps not</p> <p>13 known to me. That doesn't mean that it exists, but</p> <p>14 nitrosamines have been around since 1970s and</p> <p>15 knowledge of NDMA has been around since 1970s and</p> <p>16 WHO has been warning drug companies to look for NDMA</p> <p>17 through various guidances regarding nitrosamine.</p> <p>18 And ICH M7 guidelines specifically mentions</p> <p>19 nitrosamine as the drug of concern as they have -- as</p> <p>20 the impurities of concerns as a mutagen of concerns.</p> <p>21 So just because they haven't been shown before 2018</p> <p>22 doesn't, you know, basically give these guys a pass.</p> <p>23 Q You said that you were familiar with</p> <p>24 current good manufacturing practices. Are you aware</p> <p>25 of any current good manufacturing practice that</p>	<p style="text-align: right;">Page 180</p> <p>1 committee to -- IRAC. It's a part of WHO that</p> <p>2 specifically warns the manufacturers to look for</p> <p>3 nitrosamines and there is a specific test that they</p> <p>4 ask a lot of manufacturers to do which is called --</p> <p>5 basically it's called NAP testing, N-A-P testing,</p> <p>6 which in fact they encourage manufacturers to test</p> <p>7 their compounds to see if it's prone to developing</p> <p>8 nitrosamine. And you can look that up under NAP</p> <p>9 testing or basically WHO testing for nitrosamine</p> <p>10 and -- nitrosamine and NDMA.</p> <p>11 Just one second. I actually have somebody</p> <p>12 here. I have to give them the key to my car.</p> <p>13 MR. NIGH: Let's take a quick break.</p> <p>14 MR. GISLESON: Okay.</p> <p>15 THE VIDEOGRAPHER: Time is 3:18. We</p> <p>16 are going off the video record.</p> <p>17 (A recess was taken.)</p> <p>18 (After the recess the following</p> <p>19 occurred:)</p> <p>20 THE VIDEOGRAPHER: The time is 3:18.</p> <p>21 We are back on the video record.</p> <p>22 BY MR. GISLESON:</p> <p>23 Q Did the FDA ever issue any guidance</p> <p>24 like what you have just described from that</p> <p>25 international organization?</p>
<p style="text-align: right;">Page 179</p> <p>1 existed in or before June 2018 that required a</p> <p>2 manufacturer to test for nitrosamine impurities in</p> <p>3 pharmaceutical products?</p> <p>4 A In current and good manufacturing</p> <p>5 practices really refers to using the latest</p> <p>6 technology and in looking for impurities, making</p> <p>7 sure your drug is safe.</p> <p>8 And this is exactly to the point I was trying</p> <p>9 to make earlier, that basically the USP monograph is</p> <p>10 really just opens the door to you. So this is a</p> <p>11 common mistake and I also mention that in my</p> <p>12 presentation to this symposium that I was presenting</p> <p>13 regarding which is online, actually. You know,</p> <p>14 companies need to be looking for structures of</p> <p>15 concern which is mentioned in ICH M7, and those</p> <p>16 structures of concern should actually give you sort</p> <p>17 of a window toward compounds you should be looking</p> <p>18 for.</p> <p>19 Q Can you identify any publication that</p> <p>20 was issued before June 2018 that advised</p> <p>21 pharmaceutical manufacturers that testing for</p> <p>22 nitrosamines was part of current good manufacturing</p> <p>23 practices?</p> <p>24 MR. NIGH: Form objection.</p> <p>25 A I can refer you to international</p>	<p style="text-align: right;">Page 181</p> <p>1 A Has FDA ever issued any guidance</p> <p>2 regarding NDMA or nitrosamine?</p> <p>3 Q Similar to the international guidance</p> <p>4 you just identified.</p> <p>5 A Post 2018 or pre 2018?</p> <p>6 Q Pre 2018.</p> <p>7 A I don't know, honestly.</p> <p>8 Q You received an envelope and I think</p> <p>9 you started to open it earlier that contained some</p> <p>10 documents that we sent to you.</p> <p>11 A Right.</p> <p>12 MR. GISLESON: Bill, it's the document</p> <p>13 behind Tab 6. It's a USP monograph, this one for</p> <p>14 valsartan and --</p> <p>15 THE WITNESS: Should I open it?</p> <p>16 MR. GISLESON: Please.</p> <p>17 THE VIDEOGRAPHER: For the record, it</p> <p>18 would be marked as Exhibit 30.</p> <p>19 Q Doctor, it's behind Tab 6.</p> <p>20 MR. NIGH: Mr. Gisleson, how am I</p> <p>21 getting a copy of this document?</p> <p>22 MR. GISLESON: It's in the Exhibit</p> <p>23 File Share, Paul.</p> <p>24 MR. NIGH: Okay. Okay. Tab 6. I see</p> <p>25 it now.</p>

<p style="text-align: right;">Page 182</p> <p>1 Q Have you, Doctor, reviewed the USP</p> <p>2 monographs for all the different valsartan products</p> <p>3 that are at issue in this lawsuit?</p> <p>4 A I have reviewed a number of them, yes.</p> <p>5 Q And have you also reviewed the USP</p> <p>6 monograph for the valsartan hydrochlorothiazide</p> <p>7 tablets?</p> <p>8 A Yes, I believe so.</p> <p>9 Q Looking at Exhibit 30, is it correct</p> <p>10 that you have reviewed this USP monograph</p> <p>11 previously?</p> <p>12 A This is --</p> <p>13 Q Tab 6.</p> <p>14 A Tab 6? Okay. Okay. I need a</p> <p>15 refresher. Just give me a second.</p> <p>16 Q No problem.</p> <p>17 A Okay. I scanned through it. Go ahead</p> <p>18 with your question.</p> <p>19 Q So this USP monograph became effective</p> <p>20 as of May 1, 2015; is that right?</p> <p>21 A Okay.</p> <p>22 Q Looking at the upper left-hand corner</p> <p>23 of the first page.</p> <p>24 A Uh-huh.</p> <p>25 Q Is that correct?</p>	<p style="text-align: right;">Page 184</p> <p>1 Q When it says in here that NMT</p> <p>2 0.2 percent of any other impurity excluding</p> <p>3 valsartan-related compound A, does that include</p> <p>4 unidentified impurities?</p> <p>5 MR. NIGH: Form objection.</p> <p>6 Q Let me rephrase the question. Do you</p> <p>7 have an understanding of what's meant by not more</p> <p>8 than 0.2 percent of any other impurity?</p> <p>9 A Yes.</p> <p>10 Q What does that mean?</p> <p>11 A So it means there are other</p> <p>12 unidentified impurities potentially that should not</p> <p>13 be more than .2 percent, not more than .2 percent in</p> <p>14 the chromatogram.</p> <p>15 Q Does this monograph identified the</p> <p>16 testing procedure that a manufacturer should use to</p> <p>17 identify any impurities for this</p> <p>18 valsartan-containing drug?</p> <p>19 A So, basically, again, it goes back to</p> <p>20 this question the whole concept that I tried to</p> <p>21 explain with Clem. There are impurities that -- you</p> <p>22 could have up to maybe a hundred different</p> <p>23 impurities, John, in valsartan in this chromatogram,</p> <p>24 hundred little peaks, right?</p> <p>25 You can't identify. You can't tell which one</p>
<p style="text-align: right;">Page 183</p> <p>1 A Yes, May 2015.</p> <p>2 Q And then if you can go to the section,</p> <p>3 please, on impurities which I believe is the third</p> <p>4 or actually the fifth page.</p> <p>5 A Okay. Yes. I'm on it.</p> <p>6 Q Thank you. Does this identify</p> <p>7 specific impurities that had been identified in the</p> <p>8 valsartan and hydrochlorothiazide tablets?</p> <p>9 A It looks like it, yeah.</p> <p>10 Q And what were the specific impurities</p> <p>11 that were identified?</p> <p>12 A There is hydrochlorothiazide,</p> <p>13 benzothiadiazine related compound A. There's</p> <p>14 hydrochlorothiazide RS; there's USP valsartan RS;</p> <p>15 there's USP valsartan related compound and so forth.</p> <p>16 Q To your knowledge are there any health</p> <p>17 effects or health hazard associated with those</p> <p>18 impurities?</p> <p>19 MR. NIGH: Form objection.</p> <p>20 A I don't know.</p> <p>21 Q Then this also shows that there are</p> <p>22 acceptance criteria for those impurities that allow</p> <p>23 them to be present in the finished drug product at</p> <p>24 certainly no more than percentages; is that correct?</p> <p>25 A Right.</p>	<p style="text-align: right;">Page 185</p> <p>1 is which. You just go after picking up a few of</p> <p>2 them, you know, and USP effectively provides those</p> <p>3 impurities as reference standards and so forth, but</p> <p>4 it's really the duty of the manufacturer to look at</p> <p>5 the drug synthesis and identify and look for their</p> <p>6 structural entities of concern.</p> <p>7 You know, for example, when I look at a</p> <p>8 molecule, John, when I look at c double bond o, c</p> <p>9 carbon and chlorine, I know this chloromethyl ketone</p> <p>10 is like a tear gas. It's going to burn your eyes.</p> <p>11 If I see a molecule that has nitrite in it, I'm going</p> <p>12 to say "Oh, shit. This is going to --" pardon my</p> <p>13 language -- "this is going to be created</p> <p>14 nitrosamine."</p> <p>15 So when you look at these types of -- you</p> <p>16 know, this is like the recipe that USP gives you is</p> <p>17 more or less like a TikTok video cookbook. Have you</p> <p>18 seen these TikTok videos that give you direction on</p> <p>19 how to make, you know, a certain dish? This is a</p> <p>20 TikTok video. So what you need to do is you need to</p> <p>21 do your own due diligence. You can talk to any</p> <p>22 chemist. At my company or at any other company, they</p> <p>23 tell you this is just an entry level stuff.</p> <p>24 So it's the duty of the organic chemist at the</p> <p>25 company, synthetic organic chemist to say there are</p>

<p style="text-align: right;">Page 186</p> <p>1 structural concerns in my recipe and I am worried 2 about this impurity; therefore, look into it, okay. 3 So, this is very little and you cannot just say here 4 is TikTok video, you know, are you going to be able 5 to do this. You can't. And in fact every -- this is 6 just a starting point. 7 Q So when this refers to acceptance 8 criteria no more than 0.2 percent of any other 9 impurity, the manufacturer is to add up the 10 different unidentified impurities to determine 11 whether the total amount exceeds 0.2 percent? 12 A It means you could have lots of little 13 impurities as long as they are not over a certain 14 level, as long as they are not over .2 or 15 .1 percent, but you also need to consider if these 16 impurities are growing or not as a function of time. 17 Often we get a call from a frantic 18 manufacturer that says my drug is on the market and 19 we have -- we got report from our retained testing 20 that our drug is producing an impurity and we need to 21 figure out what that impurity is, and they tell us 22 drop everything, work on this, figure out what this 23 impurity is, you know, and we've been doing -- we 24 have done this. 25 So this is -- just to show me a few impurities</p>	<p style="text-align: right;">Page 188</p> <p>1 UV. 2 Q And it says chromatographic system? 3 A Yes. 4 Q See chromatography 621 system 5 suitability mode LC detector UV. 6 A You see the detector is UV, which 7 means it's ultra violet detector. So in my opinion, 8 USP is not following CGMP. USP is behind time and 9 these companies are hiding behind USP and I think 10 they are violating FDA's current good manufacturing 11 practices. And I have mentioned this to, you know, 12 drug manufacturers, the generic people as well and 13 they agree. I've had conversations with many of 14 them. 15 Q The test that's identified here, the 16 chromatographic system using the LC mode with a UV 17 detector, that test is the starting point, you said, 18 for what a manufacturer should do to test for 19 impurities? 20 A Exactly. 21 Q And that test does not identify 22 nitrosamine impurities, does it? 23 A No, it doesn't. You could have a lot 24 of nitrosamine in this compound and this LC test 25 will not show it. It will be invisible.</p>
<p style="text-align: right;">Page 187</p> <p>1 here, I can assure you if you look at some of the 2 chromatograms of valsartan or this, the one that 3 you're showing me, there are going to be many, many, 4 many different impurities in the chromatogram. 5 Q What is the testing method in this 6 monograph that a manufacturer should use to 7 determine whether there are any impurities? 8 A They need to follow current good 9 manufacturing practices and the current, you know 10 has -- you know, it means you gotta LCMS. HPLC 11 alone, it is a 1960's technology and unfortunately 12 FDA has been very lax about it and we've had 13 discussions with them. And companies are saying we 14 can't afford LCMS. Are you kidding me? 15 Q What is the testing method identified 16 in this specific monograph for how a manufacturer 17 should test for impurities? 18 A The testing method they are 19 identifying is HPLC with UV detector. 20 Q Is that shown on the prior page? 21 A Yeah. 22 Q Under chromatographic system? 23 A Yes. 24 Q Can you go to the prior page, please? 25 A Yeah, I am looking at it. Yeah. It's</p>	<p style="text-align: right;">Page 189</p> <p>1 Q So it's your opinion, as you said, 2 that none of the defendants' valsartan products 3 should have contained any NDMA or any NDEA; is it 4 correct that you believe FDA is wrong in permitting 5 the defendants' valsartan products to be sold so 6 long as they are -- they have less than 96 nanograms 7 of NDMA or 26.5 nanograms of NDEA? 8 MR. NIGH: Form objection. 9 A John, I cannot comment for FDA, but I 10 have stated this in our previous conversations as 11 well. I believe the levels of NDMA and NDEA should 12 be zero. These are mutagenic DNA reactive molecules 13 that knocks the hell out of your DNA, and in fact 14 the NDMA is used to create cancer in laboratory 15 animals. 16 Q So your opinion, then, directly 17 contradicts the FDA's determination that patients 18 may use the defendants valsartan products so long as 19 they contain less than either 96 nanograms of NDMA 20 or 26.5 nanograms of NDEA, correct? 21 MR. NIGH: Form objection. 22 A I'm going to reiterate what I said, 23 John. I believe in zero NDMA and NDEA. I think 24 FDA's thinking is also zero NDMA, NDEA. In my 25 opinion, perhaps maybe it's because it's political,</p>

<p style="text-align: right;">Page 190</p> <p>1 I don't know, but you're asking my opinion. I 2 cannot speak on behalf of FDA. I told you what I 3 think. 4 Q All right. Your opinion contradicts 5 the FDA's determination that these valsartan 6 products can be sold to and consumed by patients so 7 long as the nitrosamine levels are less than the 8 accepted intake levels identified by the FDA, 9 correct? 10 MR. NIGH: Form objection. Hold on. 11 Form objection. Mischaracterizes testimony. It's 12 been asked and answered multiple times. 13 MR. GISLESON: It's been asked. It 14 hasn't been answered. 15 MR. NIGH: It has been answered. It's 16 just not the way you want it answered. 17 Q Your opinion directly contradicts what 18 the FDA has said; namely, the defendant's products 19 can be sold to and consumed by patients so long as 20 the nitrosamine levels are less than the FDA's 21 determined acceptable intake levels or limits? 22 A So -- 23 MR. NIGH: Form objection. Asked and 24 answered. Mischaracterizes testimony. 25 A John, I have already mentioned what's</p>	<p style="text-align: right;">Page 192</p> <p>1 product," should be absent. 2 This is the key thing. As an initial measure, 3 FDA published levels of impurity exceeding these 4 interim levels recommended for recall before the 5 market. So they said they recommended anything above 6 certain level to be recalled, but their goal is zero. 7 Zero. I hope I've answered the question. 8 Q Doctor, what's the date of the 9 document you just read from? 10 A The date of this document? Let me 11 look it up. It's part of the submission of the -- I 12 don't know. I think that's for you guys to figure 13 out. This was -- there is no date on it. 14 Q Can you show us the first page of the 15 document, please, on the camera so we can see what 16 it says? It looks like it's a letter from the 17 Department of Health and Services. 18 A Is this part of the record? I think 19 that was submitted. 20 Q No, because I didn't offer it and I've 21 never seen it before. 22 A It was part of my testimony. It's 23 there. 24 Q Even with the presence of NDMA or 25 NDEA, do the defendant's valsartan products still</p>
<p style="text-align: right;">Page 191</p> <p>1 my opinion. I have also and FDA has also made its 2 ruling. FDA is saying 96 nanograms is the interim 3 level, but FDA in their most recent filing which 4 is -- I'd like to quote you my -- the FDA guidance 5 which is called FDA general advice and I'd like to 6 actually make -- put that as part of the record if 7 you could -- I don't know. It's page 1 and it's 8 paragraph number -- it's page 1, paragraph 2 of 9 background. I'd like to make that as part of the 10 record and I'd like to read it that to you. 11 It says, "Due to their known potent 12 carcinogenic effect and because it is feasible to 13 limit these impurities," because it's feasible to 14 limit these impurities "by taking reasonable steps," 15 meaning chemical synthesis, chemical synthetic steps 16 "to prevent or eliminate their presence, FDA has 17 determined that there is no acceptable specification 18 for nitrosamine in ARBs, API or drug product." 19 Period. Full stop. 20 This is FDA. If you want to misquote me, you 21 can go ahead and do that but, please, when you do, 22 make sure you put this next to it. Therefore, FDA 23 goes on and says, "FDA advises that nitrosamines 24 should be absent in practices; i.e. not detectable as 25 described below from ARB API and API brought</p>	<p style="text-align: right;">Page 193</p> <p>1 lower blood pressure in adults and children who 2 still use the products? 3 MR. NIGH: Form objection. 4 A John, you want my honest opinion? I 5 don't know. I don't know, because there is no 6 doubt -- I have no doubt that there is valsartan 7 molecule there, but I have no idea what the 8 interaction of NDMA, NDEA at those high levels could 9 be, because I consider NDMA and NDEA as an active 10 compound. 11 A lot of the impurities that you saw in the 12 USP monogram, a lot of the excipients: The sugar, 13 the magnesium citrate and various just binding agent 14 that makes them feel inactive, nitrosamines are 15 extremely active and so I don't know whether actually 16 they will help or hurt or they will cause certain -- 17 you know, bind something to some receptors. 18 I'm not a toxicologist. I'm not a physician 19 to know, but that's for another expert to comment. 20 Q Have you done any analysis as part of 21 your work in this case to determine whether NDMA or 22 NDEA interferes with the chemical ability of 23 valsartan to perform its intended purpose of 24 lowering blood pressure and of reducing 25 hospitalization for heart failure?</p>

<p style="text-align: right;">Page 194</p> <p>1 A We have not done any testing that</p> <p>2 shows that in DNA inhibits the effectiveness of</p> <p>3 valsartan or promotes its effectiveness of valsartan</p> <p>4 or any of that. We have not done any of those</p> <p>5 tests.</p> <p>6 Q And you also didn't do that testing</p> <p>7 for NDEA to determine whether it had such an effect,</p> <p>8 correct?</p> <p>9 A We have not done any testing to show</p> <p>10 whether NDEA promotes the pharmaco dynamics of the</p> <p>11 drug or actually inhibits the pharmaco dynamics of</p> <p>12 the drug. You could actually increase the activity</p> <p>13 of the valsartan or reduce its activity, any of</p> <p>14 those things. I don't know. We haven't done any</p> <p>15 testing. Nobody has asked us. Plaintiffs' lawyers</p> <p>16 have not asked us to do any of that.</p> <p>17 Q Nor have you used your knowledge and</p> <p>18 experience simply to analyze without testing whether</p> <p>19 NDMA or NDEA interferes with the ability of</p> <p>20 valsartan to function as intended according to the</p> <p>21 label?</p> <p>22 A We have not done any of those testings</p> <p>23 and it's not part of our plan to do any of those</p> <p>24 testings.</p> <p>25 Q Are you familiar with the phrase</p>	<p style="text-align: right;">Page 196</p> <p>1 Q In your experience do risk assessments</p> <p>2 that are submitted in connection with an ANDA to the</p> <p>3 FDA address the presence of impurities?</p> <p>4 A Sometimes. Sometimes they do,</p> <p>5 sometimes they don't. It really depends on how good</p> <p>6 at CMC a person a company has and how good a chemist</p> <p>7 they have and how they can -- if they, for example,</p> <p>8 you have a drug that all of a sudden develops odor,</p> <p>9 you know, sitting and it's causing odor or the drug</p> <p>10 is changing, you've got to do risk assessment and</p> <p>11 you need to submit it to the FDA.</p> <p>12 And those risk assessments also, I would call</p> <p>13 them a root cause analysis. They would need to go</p> <p>14 to -- they could be very narrow. They could be very</p> <p>15 extensive. It really depends on the company and it</p> <p>16 depends on the team that's involved.</p> <p>17 Q In your experience, does the drug</p> <p>18 manufacturer identify the tests that the</p> <p>19 manufacturer performed to evaluate risks associated</p> <p>20 with the drug product at issue in the ANDA?</p> <p>21 A Could you repeat your question? I</p> <p>22 kind of lost my train of thought.</p> <p>23 Q Sure. Does the drug manufacturer have</p> <p>24 to identify in the risk assessment the specific</p> <p>25 tests it performed in developing the assessment?</p>
<p style="text-align: right;">Page 195</p> <p>1 compendial standards?</p> <p>2 A Yes, I am.</p> <p>3 Q To what does that refer?</p> <p>4 A Compendial standards are standards,</p> <p>5 basically official quality standards used for drugs</p> <p>6 sold and reference standards.</p> <p>7 Q Are those the standards in the USP</p> <p>8 monographs?</p> <p>9 A Yes.</p> <p>10 Q You said that you've been involved</p> <p>11 with the preparation and submission of ANDAs,</p> <p>12 A-N-D-A-S; is that correct?</p> <p>13 A Mm-hmm.</p> <p>14 Q Yes?</p> <p>15 A Yes.</p> <p>16 Q Have you ever created a connection</p> <p>17 with a ANDA risk assessment?</p> <p>18 A Have I created a risk assessment</p> <p>19 document?</p> <p>20 Q Yes.</p> <p>21 A We've done many risk assessments in</p> <p>22 connection with and ANDA, in connection with NDA,</p> <p>23 new drug application; we have developed a risk</p> <p>24 assessment for any of our release testing. We do</p> <p>25 this on routine basis.</p>	<p style="text-align: right;">Page 197</p> <p>1 A Yeah. They should. They should. For</p> <p>2 example, at any time you change the chemical</p> <p>3 process, you change your synthetic route, any time</p> <p>4 you change the cap of -- let's say you go from glass</p> <p>5 to plastic, you need to do risk assessment; how is</p> <p>6 that going to impact your drug.</p> <p>7 You go from, you know, a prefilled syringe to</p> <p>8 another prefilled syringe, you need to do risk</p> <p>9 assessment. In this case, you know, we're getting</p> <p>10 into the really nitty gritty of sort of liability</p> <p>11 issues, Daniel but, you know, in this case they</p> <p>12 should have -- they changed the chemical process.</p> <p>13 They should have done what I call the structural sort</p> <p>14 of drugs, they should look at the structural</p> <p>15 concerned molecule and they should look at those</p> <p>16 structural concerns and say what are the chances of</p> <p>17 something going wrong with this and then do a proper</p> <p>18 risk analysis and not just brush it under the table</p> <p>19 or say this is just minor thing and go on with it.</p> <p>20 You know, using, for example, John, sodium</p> <p>21 nitrite, in the original process they didn't use</p> <p>22 sodium nitrite, whereas in the, you know, in the</p> <p>23 defendant's process almost invariably everybody used</p> <p>24 sodium nitrite. Sodium nitrate is the same molecule</p> <p>25 that you find in a lot of, you know -- it's a</p>

<p style="text-align: right;">Page 198</p> <p>1 nitrated food; you know. You get potential formation 2 of NDMA. That's where nitrosamine comes from, and 3 sodium nitrite are known to cause nitrosamine and 4 NDMA. So that's where the risk analysis went wrong. 5 MR. NIGH: I need to interject 6 something at this time. As you can see, there is a 7 seven page declaration. He has not gone into detail 8 in terms of his liability opinions and I would warn 9 counsel at this point if we are going into liability 10 opinions, we're not going to cover this ground 11 again. There's not going to be a second bite of the 12 apple at those topics. 13 MR. GISLESON: I am not going into 14 liability issues at all. I am specifically 15 addressing his point he's made a couple of times, 16 that in his view the defendants didn't do what they 17 should have done in connection with evaluating or 18 testing for NDMA and NDEA, and so I'm following up 19 on that. 20 MR. NIGH: Yeah. That's in large part 21 because of the questions that occurred earlier that 22 also touched upon liability. So to the extent we 23 are going to continue further and follow up on 24 liability, defense counsel could do so at their own 25 closing.</p>	<p style="text-align: right;">Page 200</p> <p>1 assessment in an ANDA, correct? 2 MR. NIGH: Form objection. 3 A The FDA can ask for additional tests 4 if they determine it's necessary. By and large they 5 rely on the manufacturer's own risk assessment and 6 whether the manufacturer considers that a low risk, 7 medium risk, high risk. 8 So if the manufacturer says this is low risk 9 and CMC reviewer at the FDA reviews it and if they 10 also miss it, you know, so, John, it's really a 11 question of they miss it, these guys miss it, yeah, 12 but at the end of the day it's the manufacturer's 13 responsibility. 14 Q You testified that in your view, the 15 defendant's product shouldn't contain any NDMA or 16 NDEA. Are you aware that nitrosamines have been 17 found in cosmetics? 18 A Yes, I have been aware. 19 Q Are you aware that nitrosamines have 20 been found in tobacco and cigarette smoke? 21 A Yes. 22 Q Are you aware that nitrosamines have 23 been found in drinking water? 24 A Yes, I am aware of that. 25 Q Are you aware that people consume</p>
<p style="text-align: right;">Page 199</p> <p>1 MR. TRISCHLER: And as you are aware, 2 the witness just went well beyond the scope of my 3 question to volunteer a bunch of information, which 4 is why I am also following up on it. 5 Q The bottom line, in your experience 6 the ability to instruct the manufacturer to perform 7 additional tests if the FDA believes the risk 8 assessment did not appropriately evaluate certain 9 risks; is that true? 10 MR. NIGH: Again, this is clearly 11 liability. The more you want to follow down that 12 tunnel, the more you are following up on liability 13 opinions. This is far outside the scope of his 14 declaration. 15 A Let's talk about NDMA levels, John. 16 MR. NIGH: Just because he voluntarily 17 gives information in response to one of your 18 questions that's also a liability question and 19 continue to go down that tunnel doesn't mean that 20 defense counsel is not opening the door to this 21 questioning, and they are not going to get a second 22 bite at the apple. 23 BY MR. GISLESON: 24 Q The FDA can direct additional tests if 25 it believes it appropriate when it evaluates a risk</p>	<p style="text-align: right;">Page 201</p> <p>1 processed foods that include nitrosamines? 2 A Yes, I am aware of that. 3 Q Including bacon, sausage and ham? 4 A Yes, I am aware. 5 Q Are you aware that beer can contain 6 nitrosamines? 7 A John, we have to qualify and put me on 8 record as saying the levels of nitrosamines are 9 extremely low in many of these instances. For 10 example, do you know this minimum level that's 11 acceptable to have nitrosamine in water? 12 Q It's a low level, but it exists, 13 correct? 14 A It's extremely low level. So 15 nitrosamine, every time you eat bacon, you may get a 16 little bit of nitrosamine. Your body has the 17 ability to detoxify so much. I don't want to get 18 outside of my area but, you know, low levels of 19 nitrosamine and high levels are different stories. 20 Q Those are the questions I have. Thank 21 you for your time. 22 A Thank you. 23 CROSS-EXAMINATION 24 BY MR. HARKINS: 25 Q Good evening, Dr. Najafi. Can you</p>

<p style="text-align: right;">Page 202</p> <p>1 hear me okay?</p> <p>2 A Yes.</p> <p>3 Q My name is Steven Harkins. I represent</p> <p>4 the Teva defendants and I just have a few followup</p> <p>5 questions for you here.</p> <p>6 You mentioned a few guidances today both for</p> <p>7 unidentified impurities and then for genotoxic</p> <p>8 impurities. Do you recall that?</p> <p>9 A Yes.</p> <p>10 Q Are you aware of ICH, Q3A and Q3B?</p> <p>11 A Yes, I am.</p> <p>12 Q And those provides guidance on the</p> <p>13 levels at which any impurity needs to be assessed to</p> <p>14 the extent it's not in a drug substance, right?</p> <p>15 A That's correct.</p> <p>16 Q Are you comfortable with the term</p> <p>17 qualification threshold?</p> <p>18 A Yes.</p> <p>19 Q And the qualification threshold in</p> <p>20 ICH, Q3A and Q3B defines the level at which any</p> <p>21 impurity; harmless, hazardous, needs to be assessed</p> <p>22 and then analyzed, right?</p> <p>23 A Mm-hmm.</p> <p>24 Q And unknown impurities that don't meet</p> <p>25 that threshold strictly under Q3A and Q3B don't get</p>	<p style="text-align: right;">Page 204</p> <p>1 exposure time -- so you need to consider all of that.</p> <p>2 And it goes back to the fact that you need to</p> <p>3 anticipate this impurity and then look for them.</p> <p>4 Otherwise, you know, you're chromatogram -- you have</p> <p>5 this valsartan compound is like a huge peak and then</p> <p>6 there are lots of little peaks and they don't test</p> <p>7 for it because they are actually below the levels of</p> <p>8 .1 percent, .2 percent. So they don't test for it</p> <p>9 and it doesn't require it.</p> <p>10 Q Doctor, I promise we will get to where</p> <p>11 you want to go, but I was just asking specifically</p> <p>12 under Q3A and Q3B, not subsequent guidelines which</p> <p>13 we will address in just a minute. If the</p> <p>14 qualification threshold for an unidentified impurity</p> <p>15 is not met, then testing further on those unknown</p> <p>16 impurities is not conducted pursuant to that</p> <p>17 guideline; is that right?</p> <p>18 MR. NIGH: Form objection.</p> <p>19 A This is correct with the qualification</p> <p>20 that I previously state. You need to anticipate</p> <p>21 based on structures of concern and then test some of</p> <p>22 those anticipated genotoxic compounds.</p> <p>23 Q And you previously testified that the</p> <p>24 levels for testing of genotoxic or potential</p> <p>25 genotoxic impurities are far lower?</p>
<p style="text-align: right;">Page 203</p> <p>1 assessed further --</p> <p>2 MR. NIGH: Form objection.</p> <p>3 Q -- is that correct?</p> <p>4 A No, that's not correct. Again, it</p> <p>5 goes back to -- I didn't catch. You're Steven.</p> <p>6 Steven, it goes back to looking at the structure --</p> <p>7 you know, the changes you're making; looking at the</p> <p>8 structures that are involved in the chemistry, and</p> <p>9 you need to anticipate these impurities.</p> <p>10 If you are anticipating certain genotoxic</p> <p>11 impurities, you need to test for it. It could be</p> <p>12 extremely low levels that doesn't meet the ICH</p> <p>13 guidelines you are referring to. That's where you</p> <p>14 end up going to ICH M7. ICH M7 take effect here</p> <p>15 where they talk about extremely low levels of</p> <p>16 genotoxic compound. They talk about testing those</p> <p>17 genotoxic compounds in aims test and various tests</p> <p>18 and they set limits. And it also -- it's a matter of</p> <p>19 how -- whether you have an episodic drug or a chronic</p> <p>20 drug.</p> <p>21 For example valsartan, my mom was taking</p> <p>22 valsartan for ten years. Now she is taking, you</p> <p>23 know, lisinopril for the last few years. So, you</p> <p>24 know, it really depends. Once the drug becomes a</p> <p>25 drug -- I call it life styling drug, then your</p>	<p style="text-align: right;">Page 205</p> <p>1 A Far lower, less than .1 part per</p> <p>2 million, less than 0.1 parts per million, in the</p> <p>3 case of nitrosamines, zero.</p> <p>4 Q And that guidance is at least</p> <p>5 generally laid out in ICH M7 which you laid out?</p> <p>6 A ICH M7.</p> <p>7 Q Roughly a thousand fold difference</p> <p>8 between the levels you might be looking at there?</p> <p>9 A Yeah.</p> <p>10 Q You also testified and you just</p> <p>11 mentioned again there could be 100 little identified</p> <p>12 impurities, 100 little unidentified peaks if you ran</p> <p>13 it over, correct?</p> <p>14 A Yes.</p> <p>15 Q And even an HPLC test that you used</p> <p>16 that showed those peaks, that would not be</p> <p>17 identifying and quantifying each of those impurities</p> <p>18 just by running a single test with a single set of</p> <p>19 settings, right?</p> <p>20 A You might see 100 little impurities.</p> <p>21 Those are only UV ultraviolet active compounds. You</p> <p>22 could also have another 100 that are not ultraviolet</p> <p>23 active compounds. So now you see that's where, you</p> <p>24 know, that's where people in need to anticipate</p> <p>25 certain impurities.</p>

<p style="text-align: right;">Page 206</p> <p>1 Q And to actually assess or quantify any</p> <p>2 of those, maybe, hundreds of tiny little peaks, you</p> <p>3 would need specialized testing that was specifically</p> <p>4 tuned to the impurity that you were looking at and</p> <p>5 looking for?</p> <p>6 A You need to have specialized</p> <p>7 equipment. That's where we go to CGMP, current good</p> <p>8 manufacturing practices, which really states that</p> <p>9 don't use a typewriter to type your letter. Use a</p> <p>10 computer to type your letter. You see, it's like</p> <p>11 these manufacturers are still using typewriters in</p> <p>12 the age of computer and word processor.</p> <p>13 We have GCMS which is extremely easy to</p> <p>14 operate, extremely simple and it comes with a library</p> <p>15 of molecules stored in it, so all you have to do is</p> <p>16 just point your cursor to certain impurity and it</p> <p>17 tells you the molecular weight and it tells you</p> <p>18 several possible compounds that might be.</p> <p>19 Q And you would -- I'm sorry. Are you</p> <p>20 finished?</p> <p>21 A Yes.</p> <p>22 Q So you would need a specialized test</p> <p>23 to identify, for example here, the NDMA or NDEA</p> <p>24 compound among all of those other little peaks you</p> <p>25 might see?</p>	<p style="text-align: right;">Page 208</p> <p>1 methods like the ones you used in your work for</p> <p>2 Valisure later were published eventually that</p> <p>3 allowed those specific settings to be employed to</p> <p>4 identify these impurities, correct?</p> <p>5 MR. NIGH: Form objection.</p> <p>6 A Steven, I would strike the word</p> <p>7 specialized equipment, because to someone trained in</p> <p>8 the art, specialized equipment means something that</p> <p>9 only Lawrence Livermore laboratory has or some</p> <p>10 cyclotron or something has. These are not</p> <p>11 specialized equipment, but they need to be thinking</p> <p>12 about and anticipating NDMA and NDEA and look at it,</p> <p>13 that's all.</p> <p>14 Q You're familiar with the testing</p> <p>15 methods that were published by the FDA in connection</p> <p>16 with nitrosamine recalls?</p> <p>17 A Yes, I am.</p> <p>18 Q Are you aware of those methods having</p> <p>19 been published anywhere else before they were</p> <p>20 published by the FDA in connection with the recalls</p> <p>21 in 2018?</p> <p>22 MR. NIGH: Form objection.</p> <p>23 A I am not aware, but the methods -- you</p> <p>24 know, don't need a method. You develop your</p> <p>25 methods. There are hundreds of methods for testing</p>
<p style="text-align: right;">Page 207</p> <p>1 A I wouldn't call it specialized</p> <p>2 instrument. These are routine instruments that</p> <p>3 almost every lab, every university, every company</p> <p>4 has including, in fact I would hesitate to guess</p> <p>5 that your clients -- you're representing Teva,</p> <p>6 right?</p> <p>7 Q I am.</p> <p>8 A I know for a fact that Teva has</p> <p>9 probably dozens and dozens of GCMS and LCMS at their</p> <p>10 facility.</p> <p>11 Q And simply running those tests over a</p> <p>12 drug substance without having them specifically set</p> <p>13 to the impurity that you are attempting to identify</p> <p>14 would not allow you to identify and quantify that</p> <p>15 impurity, correct?</p> <p>16 A Repeat your question? I missed it.</p> <p>17 Q Running an HPLC or any other test</p> <p>18 method over an impurity without having that machine</p> <p>19 specifically set to identify and quantify an</p> <p>20 impurity that you are trying to identify like in DNA</p> <p>21 or NDEA would not allow you to identify and quantify</p> <p>22 that impurity is that correct?</p> <p>23 A Running an HPLC would not help you</p> <p>24 with those impurities that's correct.</p> <p>25 Q And, for example, specialized test</p>	<p style="text-align: right;">Page 209</p> <p>1 NDMA if you search the literature. There is a</p> <p>2 method as early as 1970 for certain testing for</p> <p>3 NDMA; very validated, very good method.</p> <p>4 Q Doctor, imagine my question was</p> <p>5 specifically with regard to methods for identifying</p> <p>6 NDMA and NDEA which were published by the FDA in</p> <p>7 2018 with respect to the nitrosamine issue. You're</p> <p>8 familiar with those?</p> <p>9 A Yes, I am.</p> <p>10 Q And just to clarify, you're not aware</p> <p>11 of those methods having been published anywhere</p> <p>12 before that, are you?</p> <p>13 MR. NIGH: Form objection.</p> <p>14 A I am not aware of FDA publishing</p> <p>15 method for NDMA. FDA doesn't publish methods to</p> <p>16 test a lot of drugs. They get involved and, you</p> <p>17 know, basically somebody when basically something</p> <p>18 bad happens. A lot of methods that are developed,</p> <p>19 are developed by industry such as companies like us.</p> <p>20 We develop the method, we validate the method and</p> <p>21 then we submit it as part of a CMC package for NDA</p> <p>22 filing or ANDA filing to the FDA and those methods</p> <p>23 go into the system.</p> <p>24 FDA doesn't really get involved in developing</p> <p>25 testing. And then ultimately USP gets ahold of those</p>

<p style="text-align: right;">Page 210</p> <p>1 methods and puts it into their, you know, monograph.</p> <p>2 Q Doctor, you had never seen those</p> <p>3 methods published anywhere else before 2018,</p> <p>4 correct?</p> <p>5 MR. NIGH: Form objection.</p> <p>6 A I did not see FDA publishing those</p> <p>7 methods. I am not aware. There might be -- there</p> <p>8 might have been issued something before. I am not</p> <p>9 aware, but there are other methods that you can go</p> <p>10 to besides FDA for nitrosamine analysis.</p> <p>11 Q Specifically those methods and I know</p> <p>12 with respect to FDA you are not aware of anyone else</p> <p>13 publishing those mods before 2018 are you?</p> <p>14 A There are some methods outside of FDA.</p> <p>15 Q Dr. Najafi, my question is specific to</p> <p>16 those methods, just those methods for identified</p> <p>17 NDMA and NDEA. You have not seen them anywhere else</p> <p>18 FDA or otherwise before 2018, right?</p> <p>19 MR. NIGH: Form objection.</p> <p>20 A I answered the question already.</p> <p>21 Q I believe you did, but can you please</p> <p>22 just answer it for me so we have a clear record?</p> <p>23 You hadn't seen those before 2018?</p> <p>24 A I have not seen FDA publishing any</p> <p>25 methods before prior to 2018, but I may have missed</p>	<p style="text-align: right;">Page 212</p> <p>1 by GCMS by other means that are in the literature.</p> <p>2 Q Do you think you missed it or that you</p> <p>3 are wrong?</p> <p>4 A Next question, Steven.</p> <p>5 MR. NIGH: Well, hold on. Let me do</p> <p>6 the objection. I am going to say it's asked and</p> <p>7 answered. I think we asked this question many times</p> <p>8 and I will continue to warn that he doesn't have</p> <p>9 anything in his declaration about testing methods</p> <p>10 and this is really going down the liability path</p> <p>11 even further.</p> <p>12 I would just warn that to the extent</p> <p>13 he discloses opinions that starts talking about</p> <p>14 testing methods in the future, I think you all</p> <p>15 covered this topic.</p> <p>16 Q Dr. Najafi, there are other compounds</p> <p>17 within the nitrosamine class, right?</p> <p>18 A Yes.</p> <p>19 Q And the nitrosamine class is just one</p> <p>20 class of potential genotoxic compounds that are</p> <p>21 addressed by GCMS and other guidelines, correct?</p> <p>22 A Yes.</p> <p>23 Q Do you know how many classes of</p> <p>24 compounds or types of covered structure alerts there</p> <p>25 are?</p>
<p style="text-align: right;">Page 211</p> <p>1 it, but there are other methods on NDMA by other --</p> <p>2 by admissions, by industry by other people and there</p> <p>3 are multiple methods for NDEA analysis.</p> <p>4 Q Dr. Najafi, I am not asking about</p> <p>5 other methods. I am not asking about something that</p> <p>6 you haven't seen. I am asking you, Dr. Ron Najafi,</p> <p>7 had never seen any of those methods published</p> <p>8 anywhere before 2018, correct?</p> <p>9 MR. NIGH: Form objection.</p> <p>10 A Steven, I think you're trying to get</p> <p>11 your own, you know, question answered. You can go</p> <p>12 ahead and answer it.</p> <p>13 Q I am not trying to get -- you have</p> <p>14 not, correct?</p> <p>15 MR. NIGH: Form.</p> <p>16 A What would you like to hear?</p> <p>17 MR. NIGH: Form objection.</p> <p>18 Q Whether you had seen those methods</p> <p>19 published anywhere prior to 2018.</p> <p>20 A I mentioned --</p> <p>21 MR. NIGH: Form objection.</p> <p>22 A -- I have not seen FDA publishing any</p> <p>23 methods prior to 2018, but I may be wrong, you know.</p> <p>24 It requires some diligence. There are many other</p> <p>25 methods that have been published for NDMA analysis</p>	<p style="text-align: right;">Page 213</p> <p>1 A There are at least five different</p> <p>2 classes, four or five different classes of compounds</p> <p>3 by FDA. It's mentioned in the ICH guidelines.</p> <p>4 Q And there are other sources that</p> <p>5 identify potential genotoxic compounds as well,</p> <p>6 right?</p> <p>7 A Yes.</p> <p>8 Q And within each of those classes there</p> <p>9 are numerous individual compounds, right?</p> <p>10 A Correct.</p> <p>11 Q It's not your testimony that a drug</p> <p>12 manufacturer is required to perform testing for</p> <p>13 every type of potential genotoxic compound on every</p> <p>14 drug substance, is it?</p> <p>15 MR. NIGH: Form objection. We're</p> <p>16 getting way into the liability. At this point I am</p> <p>17 going to instruct him not to answer, because I think</p> <p>18 it goes far outside the scope of his opinion.</p> <p>19 Q Dr. Najafi, is it your opinion that</p> <p>20 the reason that these drugs are not equivalent to</p> <p>21 the reference listed drug is because of the presence</p> <p>22 of these impurities NDMA and NDEA?</p> <p>23 A I believe the fact that they contain</p> <p>24 these highly DNA active genotoxic impurities, it</p> <p>25 makes the drug not equivalent and not the same and I</p>

<p style="text-align: right;">Page 214</p> <p>1 think it could have, you know, significant impact on</p> <p>2 the drug's performance.</p> <p>3 Q And correct me if I'm</p> <p>4 misunderstanding, but I believe it's your testimony</p> <p>5 that someone looking at the underlying route of</p> <p>6 synthesis here should have identified the potential</p> <p>7 for this specific compound and conducted testing for</p> <p>8 it; is that right?</p> <p>9 MR. NIGH: Objection. Scope.</p> <p>10 Q I'm sorry. I didn't hear the answer.</p> <p>11 THE WITNESS: Should I answer, Daniel?</p> <p>12 MR. NIGH: Yeah, you can answer.</p> <p>13 A Someone should have anticipated. Once</p> <p>14 they changed the route of synthesis and given those</p> <p>15 structural concern the molecules of structural</p> <p>16 concern, they should have anticipated NDMA and they</p> <p>17 didn't.</p> <p>18 Also, Steven, I want to just to answer your</p> <p>19 question on methods that are available, there is EPA</p> <p>20 methods for NDMA testing that goes well before 2018,</p> <p>21 well before. There are food testing, you know,</p> <p>22 testing using NDMA for food and they are all using</p> <p>23 GCMS.</p> <p>24 Q I believe you testified actually that</p> <p>25 someone skilled in the art of chemistry, I think</p>	<p style="text-align: right;">Page 216</p> <p>1 Q They would have had the information</p> <p>2 for the Mylan product?</p> <p>3 MR. NIGH: Object to form. Outside</p> <p>4 the scope.</p> <p>5 Q I believe -- was that a "yes?"</p> <p>6 A I assume.</p> <p>7 Q Finally, I understand it's your</p> <p>8 opinion that the level of NDMA or NDEA in the</p> <p>9 product should be zero, right?</p> <p>10 A That's correct.</p> <p>11 Q And it's your opinion that any product</p> <p>12 containing NDMA or NDEA at any level is not the</p> <p>13 equivalent of RLD and, therefore, be misbranded,</p> <p>14 adulterated and should be recalled?</p> <p>15 MR. NIGH: Form objection. Outside</p> <p>16 the scope.</p> <p>17 A That is my position.</p> <p>18 Q Do you recall being shown the Valisure</p> <p>19 document which indicated that Novartis' valsartan</p> <p>20 product contained NDMA earlier?</p> <p>21 A Yes, I did see that.</p> <p>22 Q Assuming that Valisure's data showing</p> <p>23 levels of NDMA in Novartis' valsartan drug product</p> <p>24 is correct, it's your opinion that that Novartis</p> <p>25 drug product containing NDMA would be misbranded,</p>
<p style="text-align: right;">Page 215</p> <p>1 that was your phrase, it would have been obvious to</p> <p>2 look for this, right?</p> <p>3 A Right.</p> <p>4 Q FDA had access to information on the</p> <p>5 valsartan synthesis for all the API manufacturers</p> <p>6 prior to 2018, correct?</p> <p>7 A Yes, correct.</p> <p>8 Q And just to confirm your testimony</p> <p>9 that I believe you gave to Mr. Gisleson just a</p> <p>10 moment ago, you're not aware of any statements from</p> <p>11 the FDA prior to June 2018 to the manufacturers of</p> <p>12 valsartan drug products that they should just test</p> <p>13 their products for potential presence of</p> <p>14 nitrosamines, are you?</p> <p>15 A I am not aware of FDA stating that</p> <p>16 they should be aware, but WHO has been on record for</p> <p>17 stating to all manufacturers of drugs to watch for</p> <p>18 NDMA. If you have compounds of structures of</p> <p>19 interest such as sodium nitrite, they need to look</p> <p>20 for NDMA and just because FDA reviewer missed it</p> <p>21 doesn't mean the manufacturer should say okay, FDA</p> <p>22 by and large relies on the manufacturer.</p> <p>23 Q The FDA would have had the information</p> <p>24 for the ZHP product, right?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 217</p> <p>1 adulterated and should be recalled?</p> <p>2 A Assuming that Valisure's testing is</p> <p>3 correct, which I have no knowledge of whether that</p> <p>4 testing was correct and I also do not have any</p> <p>5 knowledge that Novartis is using their old synthesis</p> <p>6 and they may be using a generic drug manufacturer to</p> <p>7 make that drug product; assuming that data is</p> <p>8 correct, it's my opinion that the drug -- that NDMA</p> <p>9 should not be allowed to be sold; you know, the drug</p> <p>10 should not be allowed to be sold with NDMA.</p> <p>11 However, FDA has allowed this interim number, so it</p> <p>12 hasn't been recalled.</p> <p>13 Q But again -- and I understand your</p> <p>14 qualification, assuming that to be correct and I'm</p> <p>15 only asking it with regard to the products shown</p> <p>16 there that did, according to that information</p> <p>17 contain NDMA, it would be your opinion that that</p> <p>18 product should be recalled as misbranded and</p> <p>19 adulterated?</p> <p>20 MR. NIGH: Objection. Outside the</p> <p>21 scope of his opinion.</p> <p>22 A So assuming that misbranded, that</p> <p>23 definition is false and misleading statement, false</p> <p>24 and misleading statement, right, that's the</p> <p>25 definition of misbranded drug, and you have</p>

Page 218	Page 220
<p>1 carcinogenic impurities, then you have potentially</p> <p>2 toxic compound that, you know, people don't know</p> <p>3 about it and that is misleading to whoever is taking</p> <p>4 the drug.</p> <p>5 If I'm taking -- Steven, if I'm taking</p> <p>6 valsartan and I'm assuming this has zero NDMA in it,</p> <p>7 if I'm taking torovastatin, Lipitor, okay, I take it</p> <p>8 every day for, you know, lowering basically</p> <p>9 cholesterol and various things, I am assuming it's</p> <p>10 free of any NDMA. It has zero NDMA.</p> <p>11 Q And if that product, any product</p> <p>12 contained any level of NDMA, it would be your</p> <p>13 opinion that that product is misbranded, adulterated</p> <p>14 and should be recalled? I am just trying to</p> <p>15 understand.</p> <p>16 A That is my position. That is what I</p> <p>17 believe the product is not -- it's not being -- we</p> <p>18 are misleading the public.</p> <p>19 Q Thank you, Dr. Najafi. There is no</p> <p>20 further questions from me.</p> <p>21 THE VIDEOGRAPHER: Any other questions</p> <p>22 from the room?</p> <p>23 MR. TRISCHLER: Are there any other</p> <p>24 questions on behalf of defense counsel?</p> <p>25 MR. GISLESON: Not at this time.</p>	<p>1 A Correct.</p> <p>2 Q And you could see at the top you can</p> <p>3 see the Canada flag and it says government of</p> <p>4 Canada; do you see that?</p> <p>5 A Absolutely. Yes.</p> <p>6 Q And you can also see the words "Health</p> <p>7 Canada" there is as well. Do you see that?</p> <p>8 A I see Health Canada, yes.</p> <p>9 Q Okay. Let's go down to page 9.</p> <p>10 THE VIDEOGRAPHER: Counsel, while</p> <p>11 she's jumping to page 9, you didn't announce this is</p> <p>12 going to be marked as an exhibit.</p> <p>13 MR. NIGH: It will be marked as an</p> <p>14 exhibit.</p> <p>15 THE VIDEOGRAPHER: It will be the next</p> <p>16 one in line.</p> <p>17 MR. NIGH: I don't know what we are</p> <p>18 on, but I don't think we are using anything that has</p> <p>19 31, correct?</p> <p>20 THE VIDEOGRAPHER: Yes. We have not</p> <p>21 marked 31 yet.</p> <p>22 MR. NIGH: So I'll start at 31. This</p> <p>23 will be marked as Exhibit 31.</p> <p>24 BY MR. NIGH:</p> <p>25 Q And Doctor, do you see where it says</p>
Page 219	Page 221
<p>1 MR. NIGH: Okay. I would like to take</p> <p>2 a break. I'd like to come back in 15 minutes.</p> <p>3 THE VIDEOGRAPHER: The time is 4:16.</p> <p>4 This ends Media Unit 5.</p> <p>5 (A recess was taken.)</p> <p>6 (After the recess the following</p> <p>7 occurred:)</p> <p>8 THE VIDEOGRAPHER: The time is now</p> <p>9 4:56. This begins Media 6.</p> <p>10 CROSS-EXAMINATION</p> <p>11 BY MR. NIGH:</p> <p>12 Q Doctor, I'd like to show you a</p> <p>13 document from Canada and I will represent to you</p> <p>14 that this was a document that was disclosed as part</p> <p>15 of your materials considered and given to the</p> <p>16 defense counsel as well. Now you weren't asked</p> <p>17 about any of the health Canada testing by any of the</p> <p>18 defendants, correct?</p> <p>19 A That's correct.</p> <p>20 Q I want to draw your attention to</p> <p>21 page 9, if we can scroll down to page 9. Actually</p> <p>22 let me go to the top first. Let me get to the top</p> <p>23 here. Here you can see impurities found in certain</p> <p>24 angiotensin two receptor blocker products also known</p> <p>25 as sartans, correct?</p>	<p>1 "Novartis Pharmaceuticals" and right next to it, it</p> <p>2 shows the word Diovan?</p> <p>3 A Yes, I do.</p> <p>4 Q And do you see the ones above that</p> <p>5 refer to valsartan -- Mylan valsartan, Mylan</p> <p>6 valsartan. Do you see that?</p> <p>7 A Yes, I do.</p> <p>8 Q Now your understanding is that Diovan</p> <p>9 is the name brand of valsartan, correct?</p> <p>10 A Yes, that's correct.</p> <p>11 MR. TRISCHLER: Dan, can I get a</p> <p>12 standing objection to leading or are you going to do</p> <p>13 it one time and just ask questions the way they are</p> <p>14 supposed to be asked?</p> <p>15 MR. NIGH: You know, if you want to</p> <p>16 object to leading, you can. If you want to object</p> <p>17 to form, you can.</p> <p>18 MR. TRISCHLER: I guess I will.</p> <p>19 Objection to form.</p> <p>20 BY MR. NIGH:</p> <p>21 Q So you see the name Diovan?</p> <p>22 A Yes, I do.</p> <p>23 Q Does that refer to name brand</p> <p>24 valsartan?</p> <p>25 A Yes, it does.</p>

<p style="text-align: right;">Page 222</p> <p>1 Q And does Mylan valsartan, does that</p> <p>2 refer to generic?</p> <p>3 MR. TRISCHLER: Objecting to the form</p> <p>4 and foundation.</p> <p>5 Q And Doctor, what is the name brand of</p> <p>6 valsartan called?</p> <p>7 A Diovan.</p> <p>8 Q Okay, and next to that, let's scroll</p> <p>9 back up to the top of this page. Do you see the</p> <p>10 column that shows NDMA result and nanogram per</p> <p>11 tablet and NDEA result and nanogram per tablet?</p> <p>12 A Yes, I do.</p> <p>13 Q Let's scroll down again to November</p> <p>14 and if we can highlight where it shows not detected.</p> <p>15 A Right.</p> <p>16 Q Doctor, what does that refer to?</p> <p>17 A That refers to no NDMA or NDEA was</p> <p>18 detected for Diane.</p> <p>19 Q So Health Canada detected no NDMA or</p> <p>20 NDEA for their name brand Diovan?</p> <p>21 A Yes, that's correct.</p> <p>22 MR. NIGH: We can take this document</p> <p>23 down. Let's pull up the valsartan petition that was</p> <p>24 used earlier. I don't actually see an exhibit</p> <p>25 number in my box.</p>	<p style="text-align: right;">Page 224</p> <p>1 A That's correct.</p> <p>2 Q Now, it doesn't say Diovan, correct?</p> <p>3 A That's correct. There is no reference</p> <p>4 to Diovan.</p> <p>5 Q It says valsartan, correct?</p> <p>6 A That's correct.</p> <p>7 Q So do you know if this is Novartis</p> <p>8 name brand medication or Novartis generic drug</p> <p>9 medication?</p> <p>10 A It could be name brand or generic,</p> <p>11 Novartis generic. I have no idea.</p> <p>12 Q Looking at this, you wouldn't be able</p> <p>13 to tell us?</p> <p>14 A No.</p> <p>15 Q Okay. And also this petition doesn't</p> <p>16 test for NDEA in any way in the Novartis pills,</p> <p>17 correct?</p> <p>18 A That's correct. It only tests for</p> <p>19 NDMA and NDMS.</p> <p>20 Q Doctor, let me ask you a couple</p> <p>21 questions about chemical equivalents. A drug with</p> <p>22 20,000 nanograms of NDMA would not be chemically</p> <p>23 equivalent or the same as a drug with 14 nanograms</p> <p>24 of NDMA, correct?</p> <p>25 MR. TRISCHLER: Objection to job.</p>
<p style="text-align: right;">Page 223</p> <p>1 MS. HILTON: That was the question I</p> <p>2 have, if we actually gave this an exhibit number.</p> <p>3 THE VIDEOGRAPHER: That was 28.</p> <p>4 MR. TRISCHLER: I was going to say I</p> <p>5 thought it was 28. Thank you.</p> <p>6 BY MR. NIGH:</p> <p>7 Q Doctor, my understanding is this</p> <p>8 Valisure petition was marked 28. Do you recall</p> <p>9 seeing this petition during your questions?</p> <p>10 A Yes, I do.</p> <p>11 Q Okay. Let's scroll down to page 9.</p> <p>12 Now, Dr. Najafi, I believe earlier you said you</p> <p>13 don't believe Emery Pharma was not disclosed, its</p> <p>14 name was not disclosed as a part of this report.</p> <p>15 A Yes.</p> <p>16 Q What does that mean?</p> <p>17 A That means that we were not involved</p> <p>18 in testing any of these drugs that were listed on</p> <p>19 this petition. Typically if we do get some of these</p> <p>20 tested and corroborate data, you know, Valisure</p> <p>21 would have listed us and cited us as being involved</p> <p>22 in testing.</p> <p>23 Q Okay. And here you can see valsartan</p> <p>24 in Novartis and you can see there are a couple of</p> <p>25 these show no NDMA detected, correct?</p>	<p style="text-align: right;">Page 225</p> <p>1 Q A drug with 10,000 nanograms of NDMA</p> <p>2 would not be chemically equivalent as a drug with</p> <p>3 14 nanograms of NDMA, correct?</p> <p>4 MR. TRISCHLER: Object to form.</p> <p>5 A No.</p> <p>6 Q A drug with 96 nanograms or more of</p> <p>7 NDMA would not be chemically equivalent as a drug</p> <p>8 with 14 nanograms of NDMA, correct?</p> <p>9 A That's correct.</p> <p>10 MR. TRISCHLER: Objection to form.</p> <p>11 Q All right. Let's take a look at the</p> <p>12 next document. Now, Doctor, do you recall defense</p> <p>13 counsel showing you some -- a document that included</p> <p>14 a few pages of what's on the USP website?</p> <p>15 A Yes, I do.</p> <p>16 Q Now the USP website includes a lot</p> <p>17 more information than what was given in that</p> <p>18 document, correct?</p> <p>19 A That's correct.</p> <p>20 Q And you weren't shown this information</p> <p>21 during defense counsel's questioning from the USP</p> <p>22 website, correct?</p> <p>23 A That's correct.</p> <p>24 Q Now, this is the pathway here we can</p> <p>25 see it's USP/our work/chemical medicines and the</p>

<p style="text-align: right;">Page 226</p> <p>1 title of this document is nitrosamine impurities, 2 correct? 3 A That's correct. 4 Q And we can stroll down to the bottom 5 of this page briefly and you can see the URL 6 address, correct? 7 A Yes. That's correct. 8 Q Let's go back up. Actually, I want to 9 direct your attention to this paragraph that says 10 companies are responsible for understanding their 11 manufacturing processes which includes identifying 12 and preventing the presence of unacceptable 13 impurities. 14 This involves developing new predictive 15 approaches along with using suitable methods to 16 detect and control these impurities as well as others 17 that may arise when making changes to manufacturing 18 processes. Did I read that information correctly? 19 A Yes, you have. 20 MR. TRISCHLER: Objection to form. 21 Q Now, Doctor, according to USP, who is 22 responsible for understanding their manufacturing 23 processes? 24 A Companies are responsible for 25 understanding their manufacturing processes, not USP</p>	<p style="text-align: right;">Page 228</p> <p>1 impurities such as nitrosamines, the cohorts of 2 interest. 3 MR. NIGH: You can take this document 4 down. 5 Q Doctor, do you recall when plaintiff 6 Harkins was asking you questions about whether drugs 7 should be considered adulterated or misbranded? 8 A Yes, I do. 9 Q For the purposes of class 10 certification and the declaration that you have 11 offered, are you offering any opinions about whether 12 the defendants' valsartan containing drugs are 13 considered adulterated? 14 A I am not offering any opinion. 15 Q For the purposes of class 16 certification and the declaration that you offered, 17 are you offering any opinions about whether the 18 defendants' valsartan-containing drugs are 19 considered misbranded? 20 A No, I'm not offering any opinion. 21 Q Okay. I don't have any further 22 questions. 23 THE VIDEOGRAPHER: Counsel, just real 24 quick you didn't announce it, but the nitrosamine 25 impurities page we were just looking at, is that</p>
<p style="text-align: right;">Page 227</p> <p>1 and not FDA. 2 Q And those companies, that would be 3 referring to companies that are manufacturing drugs, 4 correct? 5 A Companies who are manufacturing drugs, 6 in this instance the companies who are manufacturing 7 ARBs. 8 Q Dr. Najafi, according to USP do they 9 state that in order to detect unacceptable 10 impurities that manufacturers can rely simply on 11 outdated technologies and methods? 12 MR. TRISCHLER: Object to form. 13 A I think reading this, this is pretty 14 clear. You want to follow CGMP guideline and CGMP 15 specifically talks about updated equipment, you 16 know, the newest technology and in this instance 17 GCMS or LCMS are not new technologies and basically 18 just as it states, the method needs to be able to 19 detect and control impurities as well as others that 20 may arise when making changes to manufacturing 21 processes, making changes to manufacturing 22 processes. And the word "predictive" is the key 23 where they say the companies need to have a 24 predictive testify involved involving developing new 25 predict testify approach to identifying, you know,</p>	<p style="text-align: right;">Page 229</p> <p>1 Exhibit 32? 2 MR. NIGH: Yes, Exhibit 32. Thank 3 you. 4 THE VIDEOGRAPHER: Excellent. 5 MR. TRISCHLER: Nothing from me, Dan, 6 subject to my prior reservations but I'm done. 7 MR. GISLESON: Nothing further from 8 Aurobindo. 9 MR HARKINS: Nothing from Teva. 10 MR. NIGH: Thank you, everybody. 11 Okay. Good night. Thank you. 12 THE VIDEOGRAPHER: The time is 5:08. 13 That concludes today's deposition. 14 (Deposition concluded 5:08 p.m.) 15 16 17 18 19 20 21 22 23 24 25</p>

[& - 2:48]

Page 1

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& 2:3,9,13 3:4,11 4:3,7,12 5:10,18 57:10	13 8:12 39:2,20 42:18,24 90:18 143:23 144:9	150:14 151:15 2/1/2022 8:9 2/3/2022 231:5 20 45:4 132:22,25 133:12 166:3 167:13 233:15 20,000 224:22 200 5:6 64:6 171:20 2000 96:12 2001 82:3 2007 96:13 2009 144:9 201 7:8 2011 96:16 99:23 2015 96:14 109:2 131:6 165:8 182:20 183:1 2016 109:2 2018 44:21 46:2 105:13 109:13 112:5 113:22 115:8,15,19 116:11,14 117:21 119:21 121:6 130:21 131:4,6 132:8 136:9 165:15 178:8,21 179:1,20 181:5,5,6 208:21 209:7 210:3,13,18,23,25 211:8,19,23 214:20 215:6,11 2019 56:18,18 66:6 70:2 71:18 73:1,4 73:10,13 74:21 75:18 76:10 77:15 78:10,21 79:10 80:5,17 84:24 116:12 132:8	2020 108:16,16 2021 48:8 82:18,21 83:16 109:13,18 111:4,24 112:6 118:22 2022 1:10,19 9:3 82:11 83:10 84:1 231:3 21 165:8 21094 230:19 214.855.8135 6:5 215.592.1500 2:15 215.977.4066 4:9 215.979.1177 3:20 219 7:9 2191 74:5 2200 6:4 2220 4:17 227 5:20 230 4:17 176:9 25 82:18,21 2500 5:6 26.5 166:4,8,19 169:10 189:7,20 27 8:14 49:23 50:5 50:14,15,25 53:7 270 4:8 27th 4:4 28 8:15 82:11 144:4,7 145:4 223:3,5,8 28202 5:20 2875 1:2 9:7 29 8:16 165:1,4 166:17,24 167:6 167:15,22 2:22 163:24 2:48 164:5
0	14 224:23 225:3,8 231:3		
0.1 47:11,19 54:18 54:20 129:19 130:1 205:2	15 84:2,7 165:6 219:2		
0.2 184:2,8 186:8 186:11	15219 3:7,13		
02109 4:4	15th 5:15		
02875 1:7	16th 5:11		
07102 5:15	17 8:13 46:13 47:1 47:9 54:15 171:3 173:11 175:9		
1	170 7:6		
1 8:4 9:3 41:8 47:9 53:25,25 84:1 85:16 118:5 130:3 157:21 182:20 186:15 191:7,8 204:8 205:1	17th 3:19		
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1,300 94:9	1800law1010.com 5:12		
1/28/2022 8:7	19087 4:9		
1/31/2022 8:8	19103 3:20		
10 7:5 60:25 131:11 146:17	19106 2:14		
10,000 225:1	1960's 187:11		
100 2:17 5:11,15 123:12 160:18 205:11,12,20,22	1970 209:2		
10017 5:11	1970s 178:14,15		
10:14 41:13	1979 178:5		
10:32 51:22	1994 94:9		
10:46 52:2	1996 92:13,16		
11 4:13	1998 92:7 96:11		
111 146:20	1:00 118:17		
11:41 89:10	1:19 1:7		
12 147:12 166:2	1:36 134:13		
12:03 89:16	2		
	2 8:5 27:11 31:9 32:11 41:14 47:5 47:6 65:15,17 82:3 89:11 105:4 121:17 125:8,22 184:13,13 186:14 191:8 204:8		

[3 - accurate]

Page 2

3	4/6/2020 8:11	7	ability 193:22
3 1:10,19 8:6 9:3	412.263.4385 3:7	7 8:10 89:24 90:7	194:19 199:6
32:11 66:20 81:23	412.560.7466 3:14	91:5,24 101:6	201:17
81:25 82:2 84:21	48 103:3 170:12	701 2:5	able 25:10,12
89:16 118:12	483 109:14,17	70130 2:6	40:17 42:18 72:14
3,000 149:16	111:5,17 112:4	704.444.3475 5:21	74:19 75:17 100:3
150:14 151:15	119:1	75 58:23	105:8 115:2
30 3:19 8:17	483s 112:14	75201 6:4	117:23 132:1
181:18 182:9	4:16 219:3	78746 2:18	164:15,17 186:4
231:17	4:24 134:8	8	224:12 227:18
300,000 55:25	4:56 219:9	8 8:11 103:23,24	absence 135:22
134:22 135:14	5	104:12 115:18	absent 168:25
137:10	5 8:8 81:23 83:10	8/2/2021 8:6	191:24 192:1
301 3:6	157:25 164:5	805591 230:20	absolute 23:8
30305 5:7	219:4	850.435.7013 2:11	113:19
30xi00224400	5,000 66:10	866.531.2048 2:18	absolutely 19:9
230:20	50 59:2 63:6 95:9	9	24:12 53:16 88:8
31 8:18 83:10	500 2:14 4:8	9 219:21,21 220:9	88:12 115:10
220:19,21,22,23	504.524.5777 2:6	220:11 223:11	161:24 175:2
312.566.4801 4:18	5066624 231:5	90 96:8	220:5
316 2:10	232:2 233:2	96 149:3,4 165:19	accept 77:21
317.231.6491 4:13	510 2:14 97:8	166:8,14 167:12	acceptable 55:6
32 8:19 229:1,2	518.724.2207 5:12	168:16,21 169:5,7	113:10 169:8,9,13
320 54:23 55:7,8	53 4:4	189:6,19 191:2	190:21 191:17
55:22 134:22	5:08 229:12,14	225:6	201:11
135:14	6	97 96:11	acceptance 45:25
320,000 54:25	6 8:9 81:23 83:25	973.757.1017 5:16	46:4,22,24 47:3,10
55:13,22	84:21 91:15	98 96:11	47:18,24 48:9,18
32502 2:11	181:13,19,24	9:09 1:20 9:2	49:4 54:17 55:17
32nd 3:13	182:13,14 219:9	9:58 41:7	129:17,21 183:22
3333 5:6	6/13/2019 8:15	a	186:7
351 22:3,7	600 5:20	a.m. 1:20 9:2	accepted 47:7
3600 6:4	6001 2:17	abbreviated 93:5	100:24 190:8
38th 3:6	60606 4:17	97:3,6 99:5,17,25	accepting 168:21
3:18 180:15,20	617.213.7000 4:5	108:7 126:23	access 48:13 215:4
4	621 176:7 188:4	127:1 129:10	accuracy 161:15
4 8:7 32:11 47:6	65 58:25	154:22 155:13	173:5 231:9
66:4 81:23 82:10	678.533.2312 5:7	156:6 157:5,10	accurate 90:7 91:6
83:15 118:17		abide 137:8	91:25 142:6
157:14,25 163:25			172:23 230:9

[accurately - answer]

Page 3

accurately 84:22 acid 133:19 acknowledge 9:17 9:20 acknowledgement 233:3 acknowledgment 231:12 acquires 46:10 acquisition 114:3 114:4,9,10 117:3 act 21:5,12,25 22:4 26:7,23 30:24 34:24 35:8 35:18 36:6 38:4 41:20,25 42:4,12 111:21 112:2 actavis 5:2,3 acting 64:18 action 119:14 230:14,17 actions 1:6 active 18:5 25:24 27:12 31:10,21,21 35:10 43:19 46:5 127:15 137:8 155:20 177:2,4,6,7 178:2 193:9,15 205:21,23 213:24 activities 67:1 158:19 activity 161:5 194:12,13 actual 27:14 add 186:9 addition 59:12 81:19 170:15 additional 89:19 174:14,18 199:7 199:24 200:3	additions 233:6 address 196:3 204:13 226:6 addressed 172:24 212:21 addressing 198:15 administer 9:21 administered 9:21 admissions 211:2 adulterated 14:11 14:13 15:23 16:4 16:25 17:20 21:6 21:8,13,18,22,24 22:7 41:19 128:1 128:8,21 216:14 217:1,19 218:13 228:7,13 adults 193:1 advice 128:10 142:23 169:2 191:5 advised 126:25 179:20 advises 168:24 191:23 advising 126:23 127:21 advocate 64:19 aerosol 176:24 affairs 156:10,14 affiliation 95:7 affirm 10:11 afford 187:14 afternoon 170:25 age 206:12 agent 168:8,9 193:13 agents 168:8 ago 65:9 83:11 102:24 103:3 120:15 144:1	162:15 170:13 171:21 215:10 agree 13:21 14:13 15:21 16:3 22:11 22:16,20 41:20 42:5,8 44:22 80:13 88:9 107:7 188:13 agreed 10:3,4 11:11 23:1 100:17 104:6 120:9,15 125:18 129:11 152:4 agreement 9:25 10:1 11:8 65:18 65:21 66:17 67:17 69:6,8,10,21 70:2 70:7,14,16 71:3,5 71:14,17 72:6,8,9 ahead 29:21 39:1 57:20 87:25 91:18 91:19 146:13 165:21 182:17 191:21 211:12 ahold 209:25 aid 4:11 aims 203:17 al 231:4 232:1 233:1 albertson's 5:17 aldrige 159:23 alert 123:21 alerted 123:20 124:20 alerting 139:8,10 139:11 alerts 212:24 alfano 3:3 allotted 231:20 allow 89:18 134:21 183:22	207:14,21 allowable 45:18 65:1 149:2 allowance 44:7,15 44:18 allowed 150:21 151:4 168:1,5 208:3 217:9,10,11 allowing 151:15 168:3 allows 129:12 135:13 alotman 3:21 alternative 19:12 alyson 3:18 amended 101:25 america 12:23 13:1,5,21 44:9 amino 67:9 amount 45:17,17 65:8 186:11 analysis 116:18 193:20 196:13 197:18 198:4 210:10 211:3,25 analyze 194:18 analyzed 202:22 anda 19:2 155:2 195:17,22 196:2 196:20 200:1 209:22 andas 100:5 195:11 angio 93:17 angiotensin 219:24 animals 189:15 announce 220:11 228:24 answer 11:22 13:13 14:3,4,5,6
--	--	---	--

[answer - aspects]

Page 4

14:20,25 15:12 16:1,8,10,13,14,23 17:5,6,14,23,25 18:15 20:16 21:17 31:4 32:21,23,25 33:15,17,18,21,21 33:24 34:2,6,9,10 34:10,11 35:15,16 35:19 37:5,6 45:9 47:21,23 50:9 57:16 59:16 60:9 60:10 61:8 70:6 73:16 76:5 77:19 78:24 79:2,16 80:1,25 81:6 94:16 101:1,25 102:15 115:24 128:13 137:6 142:12 151:8,11 155:10 165:22 168:11 210:22 211:12 213:17 214:10,11,12,18 answered 13:7,8 13:15,24 16:16 23:22,23 32:22 81:2 143:5 190:12 190:14,15,16,24 192:7 210:20 211:11 212:7 answering 15:5 161:6 169:15 answers 14:22 15:3,14 30:11 antacids 133:20 anti 133:19 antibacterial 96:18 anticipate 203:9 204:3,20 205:24	anticipated 204:22 214:13,16 anticipating 203:10 208:12 anybody 54:2 141:3 162:1 api 18:14 19:2 93:13 97:18 136:19,22 152:10 152:10 158:13,16 159:7 160:1 168:25 191:18,25 191:25 215:5 apis 136:21 apologies 135:7 168:12 apologize 98:8 135:19 apparently 82:7 appear 33:8,11 34:20,22 64:19 166:23 appeared 86:15 appended 233:7 appendix 145:16 146:15 147:4 apple 198:12 199:22 applicability 68:22 applicable 31:13 231:8 applicant 20:14 application 97:4,6 99:17,18 108:7,22 109:1 126:24 127:1,2 129:11 152:17,22 153:5 153:17,20,24 154:23 157:7,11 163:6,8 195:23	applications 93:3 93:6 99:3,6,25 100:1 155:13 156:7,23 157:5 applied 94:4 95:16 applies 23:12,18 80:4 134:24 135:3 135:15,17 apply 80:9 appointment 134:1 appreciate 21:10 74:24 139:14 160:22 approach 227:25 approaches 226:15 appropriate 13:11 13:11 77:11 199:25 appropriately 199:8 approval 154:23 approved 38:14 39:21 55:16 april 72:25 73:3,9 73:12 74:5,21 75:18 76:9 78:10 78:20 80:5,16 arb 94:12,20 169:1 191:25 arbs 94:11,18 96:24 97:1 105:13 126:20 127:4,7 168:25 191:18 227:7 area 42:22 201:18 arena 116:11 140:9 argue 75:13 76:25 151:9	argued 28:24 arguing 77:11 argument 170:19 arrangement 9:23 art 54:3,3 133:6 208:8 214:25 article 8:11,14,18 8:19 22:24 articulates 25:6 50:17 54:1 ascertain 79:9 asher 4:8 asher.block 4:10 aside 60:2 asked 13:14,17,23 14:18 17:10 23:21 29:5 36:3 47:20 52:13 65:4 77:13 77:17,21,23 91:12 102:19 119:23 121:9 141:20 142:23 148:23 153:19 155:25 160:4,6,23 163:5 169:4 190:12,13 190:23 194:15,16 212:6,7 219:16 221:14 asking 14:2 29:8 30:10 50:13 53:20 58:10 59:23 70:13 76:15 77:12,24 81:18 102:8 103:15 146:8,24 190:1 204:11 211:4,5,6 217:15 228:6 asp 110:21 aspects 74:13 111:6
--	---	--	---

[assess - believe]

Page 5

<p>assess 175:25 206:1</p> <p>assessed 202:13,21 203:1</p> <p>assessment 195:17 195:18,24 196:10 196:24,25 197:5,9 199:8 200:1,5</p> <p>assessments 195:21 196:1,12</p> <p>assign 71:22</p> <p>assist 157:9</p> <p>assisted 100:8</p> <p>associated 183:17 196:19</p> <p>assume 63:15 75:11 84:20 106:24 130:7,8 138:11 160:12 216:6</p> <p>assumed 138:22 138:24</p> <p>assuming 216:22 217:2,7,14,22 218:6,9</p> <p>assumption 139:17,21 140:3 140:10 147:21 148:15,23 160:14</p> <p>assure 159:12 187:1</p> <p>atlanta 5:7</p> <p>atmosphere 96:5</p> <p>attached 85:23 101:6 176:15 231:11</p> <p>attempt 164:20</p> <p>attempting 207:13</p> <p>attended 156:20</p> <p>attention 72:2 115:14 116:2,5</p>	<p>141:20 173:25 219:20 226:9</p> <p>attest 167:19</p> <p>attorney 10:23 230:13,15 231:13</p> <p>attorneys 9:16</p> <p>audience 160:20</p> <p>august 82:3,5</p> <p>aurobindo 3:10,10 39:14,17 71:6 117:24 162:19 171:1 229:8</p> <p>aurolife 3:10</p> <p>austin 2:18</p> <p>authorities 69:19</p> <p>authority 24:1,17 25:1 131:21</p> <p>availability 172:10</p> <p>available 72:18,20 104:16 108:11 115:12 163:12 214:19 231:6</p> <p>avenue 5:11 6:4</p> <p>award 94:8</p> <p>aware 45:4 115:22 120:1 130:16,20 130:22 131:7 136:8 178:24 199:1 200:16,18 200:22,24,25 201:2,4,5 202:10 208:18,23 209:10 209:14 210:7,9,12 215:10,15,16</p>	<p>back 17:4,11,16 27:7 31:5,6 36:8 41:13 51:21 52:3 54:13 82:15 94:9 111:16 112:7 113:2,25,25 118:1 119:20 129:4 134:13 170:14 171:2 180:21 184:19 203:5,6 204:2 219:2 222:9 226:8</p> <p>backed 109:22,24 111:14 114:6,7</p> <p>background 66:22 67:16 89:19,20 191:9</p> <p>backup 109:24 110:7 111:9,9 113:9 114:12 119:5</p> <p>bacon 201:3,15</p> <p>bad 116:21 209:18</p> <p>badger 29:19</p> <p>ballpark 142:10</p> <p>bank 143:16</p> <p>bar 54:7</p> <p>barnes 4:12</p> <p>based 37:23,24 58:5,13 125:19 140:2 148:19 167:5,11 204:21</p> <p>basic 11:7,8 75:9 75:13 175:12,20</p> <p>basically 25:5,5 27:8,21 28:10 32:12 36:13 46:21 47:4,5 50:22 78:14 102:8 104:12 108:22 112:8 119:5</p>	<p>124:22 131:22 136:17 143:2 168:23 172:8 173:9 175:25 178:22 179:9 180:5,9 184:19 195:5 209:17,17 218:8 227:17</p> <p>basis 57:18 59:17 79:11 80:7,10,16 139:21 140:10 141:4 151:5 170:13 195:25</p> <p>bat 117:23</p> <p>batch 44:1</p> <p>bated 88:25</p> <p>baylen 2:10</p> <p>bear 66:18 118:2</p> <p>bearing 75:3</p> <p>beer 201:5</p> <p>beginning 34:11 48:25 56:8 116:10</p> <p>begins 41:14 89:16 118:17 164:5 219:9</p> <p>behalf 10:3,5 81:8 190:2 218:24</p> <p>behest 123:3</p> <p>belabor 80:12 81:14</p> <p>believe 42:2 43:24 58:16 101:9 103:3 116:13 117:9 132:9,12 138:21 152:14 162:12 163:10 165:16 167:25 170:4,13 174:11 182:8 183:3 189:4,11,23 210:21 213:23 214:4,24 215:9</p>
---	---	---	---

[believe - catches]

Page 6

216:5 218:17 223:12,13 believes 199:7,25 bend 110:1 benefit 63:11 benzothiadiazine 183:13 berman 2:13 best 24:14 better 53:17 144:21 beyond 23:9,25 25:8 78:25 132:21 173:3 199:2 big 116:4 bigger 39:24 47:14 bill 82:6 84:1 144:1 171:3 181:12 billed 82:13 83:14 billing 85:4 bills 85:7,8 bind 193:17 binding 193:13 bio 19:21 20:2,7,9 20:11,19,24 21:3 26:1 biosystem 95:16 biosystems 94:5 bipc.com 5:21 bisgaard 4:7 bit 37:4 77:18 108:18 201:16 bite 198:11 199:22 block 4:8 blocker 93:18 219:24 blog 104:18 blogs 116:4 blood 193:1,24	bockius 3:11 body 25:22 201:16 bogdan 5:10 57:5 boils 79:19 bold 2:17 bond 185:8 bono 123:6,9,10 123:13 bosick 3:4 boston 4:4 bottom 62:6 199:5 226:4 bovin 57:10 box 39:16 222:25 brad 57:2,8 84:19 brakes 29:3 brand 18:23 27:17 27:20 35:21 46:9 58:5,12,14 172:12 172:15 221:9,23 222:5,20 224:8,10 brand's 28:3 35:24 36:15,17,18 branded 18:10 19:15 127:5,7 break 36:8 41:3 49:19,22 52:5,14 52:17,19 89:7 118:7,7,9,10,21 133:25 134:6 143:14 163:19,22 180:13 219:2 breaks 24:7,24,25 breath 89:1 brian 5:5 brief 79:1 81:10 briefly 170:8 226:5 bring 164:12 170:1 173:25 174:20	brings 61:22 brisbois 4:7 broader 102:11 160:23,24 brought 58:2,5,12 116:2,5 122:13 130:8 141:18 160:4 191:25 brush 197:18 btlaw.com 4:14 buchanan 5:18 bucket 85:6 bunch 133:20 199:3 burn 185:10 business 60:25 92:13 95:12 99:22 107:24 businesses 62:18 butyl 67:8,8 buy 136:20,22 buying 152:9,10	calling 80:5 camber 4:6 camera 192:15 camp 2:5 canada 8:18 219:13,17 220:3,4 220:7,8 222:19 cancel 134:2 cancer 106:24 107:13 137:16 160:8,25 168:9 189:14 cap 197:4 capable 177:11,14 car 180:12 carbon 185:9 carcinogen 49:14 carcinogenic 87:8 191:12 218:1 carcinogenicity 106:16,20 care 27:6 96:18 134:1,3 career 100:12 154:21,25 171:5 carillon 5:19 case 1:7 28:2,2 31:21 38:19 59:6 59:10,24 66:13 73:16 102:17 111:15,15 125:12 136:6 137:13 147:22 162:3 169:23 175:4,6 176:3 177:3 193:21 197:9,11 205:3 cases 58:1 catch 203:5 catches 113:6
---	--	--	--

[causation - clearly]

Page 7

causation 107:4,8 107:9,10 cause 107:13 193:16 196:13 198:3 caused 119:25 causing 94:6 137:16 168:9 196:9 ccr 230:19,20 cct 3:8 cder 156:19,20,21 156:24 157:3,6 center 5:11,14 156:19 centre 3:6,13 ceo 123:20 certain 37:17,23 37:24 111:5,8 160:5 168:3 174:2 185:19 186:13 192:6 193:16 199:8 203:10 205:25 206:16 209:2 219:23 certainly 115:6 162:5 183:24 certainty 113:19 certification 25:2 76:20 82:17,21,23 82:25 83:14 85:13 150:17 228:10,16 certified 1:17 certify 230:4,8,12 cetera 159:24 cgannon 5:16 cgmp 32:16 67:20 67:25 68:5 69:4 93:25 98:17 188:8 206:7 227:14,14	chad 176:23 chain 71:22 72:1 117:2 challenging 94:5 chance 52:7,9 103:2 141:23 chances 197:16 change 139:5,6,6 158:20,22 197:2,3 197:4 232:4,7,10 232:13,16,19 changed 197:12 214:14 changes 203:7 226:17 227:20,21 231:10 233:6 changing 196:10 characteristics 31:13 charge 176:24 charged 120:16,17 charles 2:13 charlotte 5:20 chart 164:10,11,24 chat 40:8,15,17 check 67:10 119:16 120:5,7 123:7 150:7 chemical 18:22 25:24 26:6,11,20 26:22 27:13,20,24 28:1,3,4,5 30:20 30:23,25 31:25 32:2,4 33:7,9,10 34:22,23 35:1,14 37:24 92:11 131:25 132:3 144:23,25 154:11 158:20 159:23 191:15,15 193:22 197:2,12 224:21	225:25 chemically 34:19 224:22 225:2,7 chemicals 95:21 chemist 37:23 177:23,24 185:22 185:24,25 196:6 chemistry 67:10 74:11 89:21 92:4 92:8 133:6 144:21 153:15 168:7 203:8 214:25 chicago 4:17 children 193:1 china 95:19 136:21 chlorine 185:9 chloromethyl 185:9 cholesterol 218:9 christine 5:14 christopher 5:19 christopher.henry 5:21 chromatogram 184:14,23 187:4 204:4 chromatograms 187:2 chromatographic 176:1,2,7 177:9 187:22 188:2,16 chromatography 175:18 176:4,7 177:10,16 188:4 chronic 203:19 ciba 163:13 cigarette 200:20 circumstance 161:20	citation 26:11 citations 83:6,21 84:5 cite 24:1,17 49:18 131:18 cited 26:9 132:4 169:1,2 223:21 citizen 100:15 104:4 121:20 122:12 123:11,13 123:23 124:14 148:10 160:16 161:18,18 162:1 citizens 100:21 122:3,25 123:15 124:2,9 143:14,16 143:23 145:7,10 148:17 161:22,25 162:2 citrate 193:13 civil 1:15 claim 73:22 claims 58:1,4,12 clarification 31:15 clarify 209:10 class 82:17,20,23 82:25 83:14 85:13 212:17,19,20 228:9,15 classes 212:23 213:2,2,8 clear 16:2,22 25:23 34:4 35:10 80:12 103:11 118:25 122:15 149:8 151:14,17 210:22 227:14 clearly 33:14 76:15 81:12 102:21,22 103:4 151:22 199:10
---	---	---	--

[clem - concludes]

Page 8

clem 3:4 10:2,22 15:15 39:13 74:24 137:10 140:14 149:1 162:7 184:21	colloquy 15:8 17:21 21:16 47:22 48:21,23 49:2 50:1	187:13 188:9 209:19 226:10,24 227:2,3,5,6,23	120:13 124:18 128:4,16,18 129:6 129:14 160:16 175:3 177:2,4 178:2 183:13,15 184:3 188:24 193:10 203:16 204:5 206:24 213:13 214:7 218:2
client 99:19 100:8 122:21 127:22 138:19 149:20,25 150:2 151:14 155:23	column 176:17,19 176:19,21 222:10	company 25:23 62:12 63:22,25 64:22 65:5 66:9 92:15,16 93:12,15 93:20,22 94:2,17 94:25 95:2,2 96:12,13,23 97:3 97:16,21 98:10 130:23 134:16 136:9,12,24 159:22 171:20 174:16 185:22,22 185:25 196:6,15 207:3	compounds 31:22 45:9 55:12 96:5 133:10 136:15 137:23 141:2 159:4 177:6,8 179:17 180:7 203:17 204:22 205:21,23 206:18 212:16,20,24 213:2,5,9 215:18
client's 113:7 140:23,24 151:20 155:25	comes 60:25 110:19,20 123:4 168:8 177:1 198:2 206:14	compare 167:1 compendial 195:1 195:4	computer 27:8 99:15 206:10,12
clients 28:2 67:19 99:4,7,10,15,24 125:15,21 126:2,3 126:5,7,17,22,25 127:25 128:3,7,11 149:14 150:8 151:22 155:2,17 155:23 207:5	comfort 89:7 comfortable 202:16 coming 49:6 88:22 commencement 230:4	compendium 22:10 complete 109:1 233:8 completed 15:1 231:17 completely 29:12 33:16,22 112:19 completeness 163:7 completing 92:10 compliant 68:11 69:1,1 98:19 114:21 comply 111:6,10 139:3 compound 31:22 36:20,21 43:19 46:5 47:25 48:1 48:14 87:9 88:15 88:16 110:20	concentration 137:1 concept 14:22 25:23 26:1 32:15 184:20 concepts 11:7 concern 37:20 178:19 179:15,16 185:6 204:21 214:15,16 concerned 120:13 197:15 concerns 88:17 178:20,20 186:1 197:16 concluded 229:14 concludes 41:8 89:11 163:25 229:13
close 18:20 closed 119:2 closing 119:3 198:25 cloud 111:14 112:7 113:13 119:5 clue 158:25 clues 133:2,3,5,10 139:10 cmc 108:6 153:20 153:24 154:1 155:1,1 196:6 200:9 209:21 coan 4:3 cohorts 88:16 228:1 coleen 3:19 colloquies 28:19	comment 26:2 149:24 189:9 193:19 commentary 94:23 comments 105:17 commercial 112:10 commitment 112:11 committee 180:1 common 179:11 communications 124:24 125:2,5 companies 25:7 71:15 92:12 94:4 96:8 136:15 178:16 179:14		

[concurrent - correct]

Page 9

<p>concurrent 142:18 condition 69:2 111:19 conditioned 176:19 conditions 111:25 conduct 114:23 conducted 70:3,6 70:9,23 71:19 76:10 78:1 79:8 106:15,19 204:16 214:7 confidential 73:18 100:2 101:19 105:19,23 155:15 155:21 confidentiality 125:24 confine 138:2 confirm 116:8,9 148:7 215:8 confirmed 145:19 confirms 65:22,25 confusing 121:3 conlee 2:5 connected 178:3,4 connecticut 116:3 connection 58:9 63:19 85:5 102:18 111:4 114:18 160:1 171:12,15 195:16,22,22 196:2 198:17 208:15,20 consent 9:23 consider 100:18 158:5 161:22 163:2 177:25 186:15 193:9 204:1</p>	<p>considered 11:14 11:24 12:7,18 37:20 219:15 228:7,13,19 considers 200:6 consistent 80:16 116:25 129:5 constitute 111:20 constituted 112:1 constitutes 21:13 26:11 consult 137:24 consultant 57:13 57:22,23 63:20 64:3 66:1,25 71:17 157:9 consulting 59:19 consume 200:25 consumed 190:6 190:19 consuming 165:24 contact 119:22 174:17 contacted 120:6 contacts 172:12 contain 11:11,19 13:1,5 21:6,12 58:20 79:20 88:14 129:14 138:9 140:3 152:1 168:2 173:6 178:9 189:19 200:15 201:5 213:23 217:17 contained 79:3,21 86:16,24 138:23 147:23 148:16 162:9 178:12 181:9 189:3 216:20 218:12</p>	<p>containing 58:7 70:4,17,24 71:10 79:19 80:15,18,20 138:19 150:15 166:23 184:18 216:12,25 228:12 228:18 contains 11:14,18 11:25 12:5,9,13,16 13:21 14:8 15:16 15:18 42:9 61:23 104:9 128:4,16 136:25 138:6 contaminated 21:9 151:23 content 80:16 149:9 165:19 166:13,18 169:5 contents 126:23 127:1 142:5 continue 39:16 90:4 103:1 112:9 112:10 159:10 177:5 198:23 199:19 212:8 continued 3:1 4:1 5:1 6:1 contract 60:24 68:25 98:19 107:25 110:18 contradicts 189:17 190:4,17 control 226:16 227:19 controlled 45:13 controls 78:18 153:15 conveniently 126:2 conversation 29:13 176:14</p>	<p>conversations 188:13 189:10 convert 54:24 cookbook 185:17 copies 231:14 copy 39:20 85:16 89:23 90:10,25 181:21 core 139:24 162:25 corner 182:22 corporation 62:21 62:24 63:1 correct 11:4,5 12:24 18:15 19:24 20:14 33:5,6 47:11 62:4,20,22 63:7,18 65:20,23 66:7 67:3,23 72:6 80:8 82:3,4 85:23 85:24 86:18 87:1 89:21,22 90:7,9 92:1,6,9,14,18 96:17,20 97:19 98:5,8,11,12 104:13,14,21 105:14,15 107:8 111:7,22 113:22 114:3,9 115:4 116:22 126:24 130:6,10 134:18 142:19 143:10 144:17 145:4,5,8 147:1,5,14,17,19 148:24,25 154:18 158:14 161:10 182:9,25 183:24 189:4,20 190:9 194:8 195:12 200:1 201:13 202:15 203:3,4</p>
--	---	---	--

[correct - declaration]

Page 10

204:19 205:13 207:15,22,24 208:4 210:4 211:8 211:14 212:21 213:10 214:3 215:6,7 216:10,24 217:3,4,8,14 219:18,19,25 220:1,19 221:9,10 222:21 223:25 224:1,2,3,5,6,17 224:18,24 225:3,8 225:9,18,19,22,23 226:2,3,6,7 227:4 233:8 corrections 233:6 correctly 65:19 67:22 125:16 158:1 165:12 226:18 corroborate 143:8 146:12 148:11,20 174:21 223:20 corroborated 120:19 143:10 146:1,6 148:7 160:18 cosmetic 21:5,12 21:25 22:3 26:7 26:23 30:24 34:24 35:8,18 36:6 38:4 41:20,25 42:3,12 111:21 112:2 cosmetics 200:17 counsel 9:11,22 39:14 41:14 45:21 57:13 75:3 165:9 198:9,24 199:20 218:24 219:16 220:10 225:13 228:23 230:13,16	231:14 counsel's 225:21 counter 133:21 couple 32:10 118:19 134:3 144:11 173:17 174:19 198:15 223:24 224:20 course 169:21 court 1:1,15,17 9:6,9,12,14,16 10:6,9,15,25 39:1 45:21 75:14 230:3 cousin 133:18 cover 89:18 164:8 198:10 covered 118:20 212:15,24 covering 11:7 cp 92:16,21,24 93:2,5,8,11,15,19 93:21,23 94:1,16 94:20,23 95:1,3,4 95:5,7,9,12,14,17 96:10 cplab.com 95:22 create 158:23 189:14 created 76:9 185:13 195:16,18 credentials 90:8 criteria 23:20 46:1 46:4,22,24 47:3,7 47:10,18,24 48:10 48:18 49:4 50:21 54:17 55:18 129:18,21 183:22 186:8 crierias 161:20 critical 108:5	criticized 149:14 cross 7:6,8,9 170:23 201:23 219:10 cs 231:15 cschaffer 2:15 csr 1:17 culbertson 4:3 curiosity 110:11 current 32:16,17 67:25 91:5,24 119:1 178:24,25 179:4,22 187:8,9 188:10 206:7 currently 67:17 164:10 165:7 168:20 cursor 206:16 custody 71:23 72:1 114:13 117:3 cut 23:15 cv 89:23 90:5,10 91:5 92:19 101:6 108:13 cvs 4:11 cwhill 3:21 cyclotron 208:10 cygnet 4:2 d d 195:12 d.stanoch 2:7 dallas 6:4 dan 76:12 77:12 89:6 134:4 155:12 221:11 229:5 daniel 2:10 10:4 29:5 40:11 57:2,3 57:3 59:18 75:7 84:19 101:23 102:7 128:25 140:19 197:11	214:11 231:1 data 109:22,23 110:7 111:9,9,13 111:16 112:3,3,7,8 112:19,23,23 113:2,4,5,7,12,14 113:18,23 114:2,4 114:5,9,13 117:3,3 117:4 120:11,12 120:19 121:21,22 143:3,8,11 146:12 148:17,20,21,22 148:24,25 152:3 163:17 216:22 217:7 223:20 date 62:1 81:13 83:19 91:5,24 192:8,10,13 230:11 232:24 233:12 dated 82:3,10 83:10 84:1 144:9 165:8 david 2:4 120:6 davis 2:16,17 92:8 dawkins 1:17 9:10 9:15 230:2,19 day 17:11 24:8 98:10 165:24 168:17 169:6,11 171:8 200:12 218:8 233:15 days 83:11 231:17 deal 139:12 decision 122:24 declaration 8:4 61:22 83:15,19 85:15,16,22 86:14 86:16,20,25 87:3 87:12,25 88:4,10 103:8 117:15
---	--	--	---

[declaration - diovan]

Page 11

118:1,4 121:14,15 121:17 125:9 139:23 150:17,25 151:5 157:15 162:3,9,11,16,24 198:7 199:14 212:9 228:10,16 declare 233:4 deemed 14:13 42:4 233:6 defendant 4:2,6,15 5:17 6:2 80:19 defendant's 138:23 190:18 192:25 197:23 200:15 defendants 3:2,10 3:16 4:11 5:2 10:3 10:24 28:24 71:11 126:7,10,13 127:3 138:20 151:2 152:12 162:18 163:11 189:2,5,18 198:16 202:4 219:18 228:12,18 defense 198:24 199:20 218:24 219:16 225:12,21 define 38:2 defined 22:7 31:1 35:17 36:6,10,25 38:3 41:21,24 42:2 defines 202:20 definition 21:6,10 21:13,23 22:2,15 22:17,20 26:19,22 34:23 35:1,6,9 38:5,7 41:19 42:6 42:10,11 107:10 161:11,13 217:23	217:25 degradation 44:2 degree 103:14 deletes 114:5 demonstrate 31:10,20 department 192:17 depending 176:18 depends 69:3 196:5,15,16 203:24 deponent 231:13 233:3 depose 103:2 deposing 231:13 deposition 1:9,12 1:14 9:4,17,18,19 10:12 17:15 28:18 56:9 84:9,12,16 102:17,18,19 103:1 121:12 160:3,6 169:22 170:14 229:13,14 describe 54:10 74:19 75:17 157:15 158:5 described 50:20 80:4 98:14 102:21 180:24 191:25 description 8:2 designated 11:3 107:3 desire 117:1 desk 27:2 detail 198:7 details 72:11 detect 226:16 227:9,19 detectable 168:25 191:24	detected 177:3 222:14,18,19 223:25 detecting 177:14 detection 49:16 177:22 detector 176:8,22 176:22,23,23,24 176:25,25 177:1,2 177:10,22 187:19 188:5,6,7,17 detectors 177:13 determination 189:17 190:5 determinations 167:11 determinative 77:5 determine 19:19 28:7 73:21 186:10 187:7 193:21 194:7 200:4 determined 18:1 19:17 190:21 191:17 detoxify 201:17 develop 92:24 97:11 98:22 114:24 132:6,14 159:11 171:23 208:24 209:20 developed 68:7,23 78:3 132:15 159:6 159:9 195:23 209:18,19 developing 18:14 180:7 196:25 209:24 226:14 227:24 development 158:18	develops 172:16 196:8 device 97:9 devoted 84:23 diagnose 106:24 diane 222:18 dictate 135:23 difference 129:2,5 205:7 differences 128:20 different 17:10 19:1,2,8,23 20:5 27:22,23 28:4 35:25 36:19 46:21 46:22 66:13 71:2 78:1 90:15,16,23 146:23 153:7,11 154:9 174:5 182:2 184:22 186:10 187:4 201:19 213:1,2 differently 77:18 77:21,24 differs 22:8 difficult 24:13 diligence 19:18 109:23 158:24 159:2 185:21 211:24 dimethyl 67:14 137:14 dimethylforamide 144:18 dimethylformam... 144:19 145:3 diovan 8:12 38:20 39:3,21 42:17 43:1 79:21 125:3 130:15 138:7,10 138:24 148:16 152:13,17,22
--	---	--	---

[diovan - drug]

Page 12

154:5,18 163:6,14 221:2,8,21 222:7 222:20 224:2,4 diphenyl 133:22 direct 7:5 10:16 199:24 226:9 direction 185:18 directly 189:16 190:17 disagree 17:22 76:12 79:6 81:12 103:8 disagreement 79:14 disappeared 118:3 disclose 44:1,3 61:14 126:5 159:1 disclosed 40:3 57:19 59:20,23 60:1,8,13,21 61:5 61:18 62:9 76:1 79:7 103:20 105:12,22 153:8 154:12 155:24 169:23 219:14 223:13,14 discloses 42:25 46:10 212:13 disclosure 104:20 125:9 discover 77:7 discovered 131:7 discuss 121:13 discussed 28:17 discussing 84:16 discussions 187:13 dish 185:19 dispensed 38:11 display 65:14 dispute 75:12	disrespect 79:13 distinguish 145:1 distribute 95:21 95:21 district 1:1,1 9:6,6 10:25,25 division 97:9 157:13 dmb 98:19 dmf 67:2,12,13,14 99:8,9,11,18 100:9 144:15,18 145:1 145:18 dna 137:15 189:12 189:13 194:2 207:20 213:24 dnigh 2:12 231:2 doctor 41:18 52:5 60:10 81:22 89:18 91:16 106:5,6 107:1,5 118:21 121:18 134:15 139:20 149:9 150:10 151:25 158:12 164:7 165:4 170:25 171:5 181:19 182:1 192:8 204:10 209:4 210:2 219:12 220:25 222:5,16 223:7 224:20 225:12 226:21 228:5 doctors 142:12 document 1:5 36:25 40:2 41:15 46:15 48:13 50:25 53:10,16,19 82:6 86:9 87:19,21 90:17 101:25	102:15 103:14 104:19,24 105:5 146:25 164:21 165:6 169:2 181:12,21 192:9 192:10,15 195:19 216:19 219:13,14 222:22 225:12,13 225:18 226:1 228:3 documentation 112:24 documentations 167:3 documented 142:4 documents 40:15 50:24 81:21 83:4 103:15 152:18,21 153:3,7,11 154:9 162:10,13,15,20 163:3,18 164:8 169:18,19 170:2 170:11,20 181:10 doing 28:25 29:1 29:17,24,25 72:23 79:10 105:21 113:21 115:20 116:18 123:8 130:17 131:14 174:16 186:23 dollar 65:8 door 179:10 199:20 dosage 165:23 dose 150:3 double 150:7 185:8 doubt 193:6,6 download 40:18 downloading 144:3	dozen 59:7,11 dozens 207:9,9 dr 33:17 39:14,15 40:17 51:9 52:20 75:1 155:7 162:3 168:10 201:25 210:15 211:4,6 212:16 213:19 218:19 223:12 227:8 draft 103:15 104:10 drafted 101:10,13 102:8 draw 40:14 116:8 219:20 drinking 200:23 drive 109:25 driven 114:22 drop 85:6 186:22 drug 11:11,13,13 11:18,24 12:4,5,7 12:12,16,18,22,22 12:25 13:4,19 14:7,7,11 15:15,15 15:23 16:4,24 17:20 18:6,11,23 19:3,7,14,15,18 20:1,7,14,18,22 21:5,12,24,24 22:3 22:8 23:4,7,18 26:7,23 27:8 30:24 31:7,14,17 31:24 32:5 34:24 35:7,12,18 36:6 37:9,10,13,14 38:4 38:11,18 41:19,25 42:3,4,8,12,14,14 43:13,21 44:8,15 44:19 45:2,3 46:6 55:6,16,22 58:13
---	---	---	---

[drug - entitled]

Page 13

58:17,18 59:5,5,8 59:9 73:25 86:18 87:6,10,13 88:6,7 88:14 92:25 93:2 93:5,9,13 94:3,3 97:4,4,6,7,8 98:23 99:2,6,17,18,25 100:1 107:17,19 107:23 108:2,7,9 110:15,17,24 111:20 112:1 123:7,21 126:18 126:24 127:1,2,10 128:21 129:11,13 130:16 134:16 136:5,24 137:2,3 138:22 140:2 145:1 149:9 151:25 152:2,16 152:21 153:5,16 153:20,24 154:22 154:24 155:13 156:5,6,10,19,22 156:23 157:4,5,7 157:10,13,16 158:7,14,16,17 159:7,12,16,19,20 159:25 160:1,8,25 161:9 163:6,8 167:6,14,22 171:10,10,22,23 172:9,10,11,14,24 177:25 178:16,19 179:7 183:23 184:18 185:5 186:18,20 188:12 191:18 194:11,12 195:23 196:8,9,17 196:20,23 197:6 202:14 203:19,20 203:24,25,25	207:12 213:11,14 213:21,25 215:12 216:23,25 217:6,7 217:8,9,25 218:4 224:8,21,23 225:1 225:2,6,7 drug's 214:2 drugs 20:6 32:5 58:14 128:1 132:17,22,23,25 133:12 137:7 138:8,9,18,21 139:25 140:3 141:3 155:16,17 155:18,19 157:9 172:9 178:8,11 195:5 197:14 209:16 213:20 215:17 223:18 227:3,5 228:6,12 228:18 duane 3:18 duanemorris.com 3:21,21 due 19:18 99:14 109:23 124:17 158:24 159:2 185:21 191:11 duly 230:5 duties 107:22 duty 27:9 31:8,18 185:4,24 dynamics 194:10 194:11	138:17 165:17 179:9 181:9 198:21 216:20 222:24 223:12 early 105:13 108:16 113:22 115:8,19 119:21 119:21 141:24 143:12,13 209:2 earthquake 111:12,15 113:7 easing 172:10 east 4:8 easy 139:19 206:13 eat 201:15 ecological 95:15 95:24 96:6 education 89:20 effect 168:17 169:6,8,11 191:12 194:7 203:14 effective 182:19 effectively 68:18 93:22 124:19 159:3 171:9 172:10 185:2 effectiveness 194:2,3 effects 183:17 either 21:20 26:22 27:16 35:21 36:14 61:19 166:13,19 175:18 189:19 elaborate 121:19 eliminate 191:16 ellie 6:3 ellie.norris 6:5 else's 73:17 elt 176:25	email 40:11 emea 131:23 emery 8:5,6,7,8,9 8:11 62:19 63:24 64:2,23 67:1 68:10 70:15,23 76:9 86:1 96:14 96:15 97:25 98:9 98:15,18,22,24,25 99:2,5,8,21 104:13 105:11 108:18 110:14 111:5 112:16 118:22 122:7,17,20 123:20 125:14 171:9,10 223:13 employ 126:1 employed 125:11 156:15,17 208:3 employee 230:13 230:15 employees 100:11 encourage 180:6 ended 152:11 ends 118:12 219:4 engaged 116:12 engagement 65:22 65:25 116:10 engaging 66:25 engineering 131:25 132:4 entered 70:1 71:16 entering 70:14 72:5 entire 53:10 entirely 19:6 123:25 entities 185:6 entitled 1:14 15:2 15:13 16:8 73:20 75:12 76:15 151:7
	e		
	e 2:1,1,13 3:1,1 4:1 4:1 5:1,1 6:1,1 63:13 230:1,1 232:3,3,3 earlier 36:4 41:18 83:3 112:23		

[entitled - experience]

Page 14

164:10 entry 70:15 174:6 185:23 envelope 181:8 environment 98:21 122:18,22 environmental 96:2 epa 214:19 epidemiologist 106:10,13 161:5 epidemiology 106:12 episodic 203:19 equally 80:9 equipment 68:15 206:7 208:7,8,11 227:15 equivalence 20:7,9 20:12,20,24 21:3 26:20,22 31:19 34:21,22,24 35:2,6 35:7,14,17 36:4,5 36:10,24 equivalent 19:23 20:4 25:18 26:6 33:8,10 34:19 79:20 88:6 137:2 138:7,21 140:1 152:1 154:24 213:20,25 216:13 224:23 225:2,7 equivalents 19:21 20:3 25:24,25,25 26:1,1,11 30:21,23 31:1 33:9 224:21 errata 231:11,13 231:17 erratas 231:15 esq 2:4,4,5,10,13 2:17 3:4,5,5,12,12	3:18,19 4:3,8,12 4:16 5:4,5,5,10,14 5:19 6:3 231:1 essentially 79:3 83:3 88:16 99:11 119:6 143:5 171:21 establish 19:20 20:2,6,23 21:3 30:22 37:8 established 11:10 20:12 27:16,17,18 31:2 35:2 44:22 45:5 49:16 76:8 76:13 78:16 81:4 167:8 168:13 establishment 119:17 estimate 59:4 et 159:24 231:4 232:1 233:1 european 69:19 131:21 evaluate 196:19 199:8 evaluates 199:25 evaluating 129:10 156:22 157:4,7,10 198:17 evaluation 141:21 156:19 evaporation 96:1 96:3 evening 201:25 event 61:25 eventually 94:24 98:9 208:2 everybody 172:16 197:23 229:10 everyday 76:14	exact 18:10,12,22 53:2 64:5 65:8 167:18 exactly 22:5 27:13 27:19 72:21 82:19 84:10 130:11 179:8 188:20 examination 1:13 7:5,6,8,9 10:16 170:23 201:23 219:10 230:5 examine 102:14 example 172:11 175:6 178:3 185:7 196:7 197:2,20 201:10 203:21 206:23 207:25 exceeding 192:3 exceeds 186:11 excellent 229:4 excipients 32:7,7 193:12 excluding 184:2 excuse 13:13 45:20 125:9 127:8 131:2 169:19 exercise 24:23 exforge 38:22 79:21 125:6 130:15 138:7,11 138:24 148:15 152:13 163:9,9 exhibit 8:4,5,6,7,8 8:9,10,11,12,13,14 8:15,16,17,18,19 39:2,20 42:18,24 46:13 47:1,9 49:23 50:5,14,15 50:25 51:9,10 53:7,25 54:15 65:15,17 66:5	81:25 82:2,10 83:10,25 85:16 89:24 90:7 91:5 91:10,24 101:6 103:23,24 104:12 115:18 118:5 143:24 144:4,7 145:4 157:21 164:24,25 165:4 166:17,24 167:6 167:15,22 171:3 173:11 175:9 181:18,22 182:9 220:12,14,23 222:24 223:2 229:1,2 exhibits 8:1 38:25 40:18 81:23 84:21 118:2 164:16 existed 179:1 existence 103:21 existing 77:14 78:5,11 95:1 exists 23:12 95:5 178:13 201:12 expect 27:24 28:4 expectation 50:18 54:4 expectations 54:1 54:2,6 157:16 158:5,6 expense 123:2 124:1 expenses 63:16 experience 94:11 100:4 108:2 172:18,22 173:4,8 174:9,12,24 177:11,13 194:18 196:1,17 199:5
--	--	--	--

[expert - filing]

Page 15

expert 8:4 11:3 25:2 28:10 37:23 56:10 59:24 60:5 60:8,12 61:6,14,19 61:20 62:9 66:25 79:8 82:23 83:2,5 85:1 88:22 103:6 149:21 168:4 193:19 expertise 106:11 experts 59:25 explain 107:9 136:2 139:18 141:18 184:21 exploration 151:4 export 95:19 exposure 107:12 204:1 expressed 86:19 extensive 196:15 extent 170:19 171:6,18 172:3 198:22 202:14 212:12 extremely 11:20 15:18 112:24 193:15 201:9,14 203:12,15 206:13 206:14 eye 96:18 eyes 185:10	158:11 168:7 173:18 180:6 186:5 189:13 204:2 207:4,8 213:23 facts 75:9,13 77:1 factual 79:12 failing 124:12 fails 231:19 failure 193:25 fair 64:13 106:9 106:24 128:19 138:1 139:19 140:18,21 160:14 fairly 80:16 176:12 fairness 73:20 falanga 5:13 falkenberg 4:16 falkenbergives.c... 4:18 fall 22:9 121:5 false 42:5,15 217:23,23 familiar 22:2,6 38:4 54:2 90:5 156:18 164:11 178:23 194:25 208:14 209:8 famotidine 133:19 fantastic 168:9 far 24:25 72:12 78:25 91:4 102:13 103:7 127:4 136:3 136:14,16 139:22 150:16,23 151:11 151:18 166:2 167:14,17 168:20 169:7,12 170:10 170:21 199:13 204:25 205:1	213:18 faranghi 63:9 fast 23:15 fda 18:4,9,21 19:10,13,21 20:2 20:19 26:8,24,24 30:25 35:3 36:10 36:10,25,25 37:8 37:12 38:5,6,14 39:21 43:14,25,25 44:3,23 45:5 49:17 68:10,11 69:18 78:14 93:24 97:9 98:18,18 99:12 100:16,17 104:6,6 108:19,23 108:23,24 109:8 109:11 111:1,4,17 111:24 112:17 114:20,20 115:14 115:21 118:22 120:1,4,24 121:2,4 122:20 123:22 124:19 129:8,12 137:16 141:15 144:15 150:6,7,8,8 154:23 155:14 156:16,17 157:9 157:13,15 158:19 159:2 160:17,18 162:6 167:9,10,20 168:2,13,20,23,24 169:1 171:16,18 172:1,3,5 175:1,6 180:23 181:1 187:12 189:4,9 190:2,8,18 191:1,2 191:3,4,5,16,20,22 191:23 192:3 196:3,11 199:7,24 200:3,9 208:15,20	209:6,14,15,22,24 210:6,10,12,14,18 210:24 211:22 213:3 215:4,11,15 215:20,21,23 217:11 227:1 fda's 130:18 168:3 168:23 188:10 189:17,24 190:5 190:20 fdf 101:4 feasible 191:12,13 february 1:10,19 9:3 84:1 231:3 federal 12:8 27:9 31:8,18 feed 40:1 feel 101:7 193:14 fees 17:12,16 63:21 fell 124:21 fhs 3:8 field 89:21 106:11 161:15 fifth 183:4 fifty 63:4,4 figure 186:21,22 192:12 file 40:4,16 43:25 61:22 107:17,20 122:3 144:14 160:1 164:9 165:9 181:23 filed 100:15 101:2 123:1,23 124:14 160:17 files 93:9 filing 44:4 101:4 104:3 191:3 209:22,22
f			
f 63:12 230:1 facility 108:1 109:9 113:6 114:1 114:12 207:10 fact 11:10 13:4 19:9 77:2 79:24 94:5 129:8,24 134:20 140:22 143:7 148:9 152:9			

[filings - fume]

Page 16

filings 99:18 155:1	fl 2:11	18:8,16 19:4 21:7	formulation 93:16
filled 109:17	flag 220:3	22:18 24:22 25:20	94:17 96:23 97:19
final 83:14,24	flip 90:14 91:11,14	37:3,6 42:1,13	138:6 156:7
finalized 61:19	146:16 157:24	43:9 46:3 47:21	158:14 159:8
finally 216:7	flipping 90:19,21	49:9 50:7 53:9	formulations
financially 230:16	floor 3:6,13 4:4	59:15 65:17 101:8	148:16
find 24:8 25:9,10	5:11,15	109:14,16 111:17	forth 22:9 46:25
25:12,13,16 52:24	focus 97:10	115:23 121:8	54:11 88:10
53:5 66:18 118:3	folded 94:24	123:22 126:6	183:15 185:3
164:19 173:24	follow 68:25 78:13	128:23 133:11	230:11
197:25	117:1 150:21	135:2,5,16 136:1	forthright 154:16
finding 94:7 111:5	151:16 171:9	136:13 137:5	found 9:5 50:10,11
124:18	187:8 198:23	139:1 146:14	104:5 111:24
findings 100:18	199:11 227:14	147:25 148:2	131:9 136:18
142:5	followed 76:17	149:19 154:19	143:20 147:16
fine 17:15 129:7	114:18	168:19 172:6,20	173:13 174:18
fingers 24:5	following 35:21,23	172:25 173:23	178:8 200:17,20
finish 24:10,10,15	36:14,16,18 41:10	177:19 178:10	200:23 219:23
33:16 65:24 156:3	51:25 69:14,15	179:24 183:19	foundation 222:4
168:11	78:17 89:13 93:21	184:5 189:8,21	four 170:9,16
finished 33:15	109:15 112:14	190:10,11,23	213:2
44:6 94:13 183:23	118:14 126:1	193:3 200:2 203:2	frame 109:3
206:20	134:10 158:21	204:18 208:5,22	framed 138:17
finishes 155:8	164:2 180:18	209:13 210:5,19	francisco 92:5
fire 111:15 113:6	188:8 198:18	211:9,15,17,21	frank 3:5 40:5,6,7
firm 9:8,10 57:10	199:4,12 219:6	213:15 216:3,15	63:12 120:3
71:3 73:23,24	followup 118:19	221:17,19 222:3	143:21,22 164:15
74:2,4,8 81:22	170:6 202:4	225:4,10 226:20	164:17,23
116:12	food 21:5,12,24	227:12	frantic 186:17
firms 61:2,3 74:5	22:3 26:7,23	formamide 144:20	free 105:20 218:10
first 25:21 33:19	30:24 34:24 35:7	formation 125:13	front 38:8 87:23
56:12,15 58:3	35:18 36:6 38:4	128:18 133:5	121:18 164:18
63:13 72:23 86:16	41:19,25 42:3,12	198:1	167:3
88:18 112:4,5	111:20 112:1	formed 46:8	frozen 87:16
121:16 144:11	198:1 214:21,22	171:20	fulbright 6:3
146:16 151:19	foods 201:1	forming 133:9	full 10:7 38:9 40:3
176:6 182:23	forbid 113:6	forms 139:21	78:17 88:22 105:7
192:14 219:22	foregoing 230:8	formulate 97:1	191:19 205:7
five 89:7 90:22	233:5	formulating	fumarate 67:14
118:7 146:11	form 11:16 12:2	125:12 162:8,11	fume 96:1
149:10 213:1,2	12:10,20 14:14	162:15	

[function - goes]

Page 17

function 32:6 98:15 186:16 194:20 funding 123:6 funnel 95:15,24 96:7 further 9:20 79:16 81:5,6 169:17 170:4,17 198:23 203:1 204:15 212:11 218:20 228:21 229:7 230:8,12 furthermore 137:16 future 67:19 69:22 81:13 212:14	generic 18:5,9,22 18:23,25 19:7,12 19:14,18,20,23 20:1,4,6,7,14,18 20:23 25:18 27:8 27:18,19 30:21 31:7,9,17,20 32:19 58:5,13,15 79:20 87:13 88:5,14 97:14,15,18 107:23 108:10 126:18 127:6,6,7,8 127:9,9,21,25 128:8 138:6,9,18 138:23 139:25 151:25 152:13 154:24 156:7,10 156:14 157:9,12 157:16 158:7,14 158:16 159:7,12 159:16,19 160:1 160:19,21 172:9 172:10 188:12 217:6 222:2 224:8 224:10,11 generics 127:19 genotoxic 28:8 36:20,21 37:19 43:5 44:20 45:9 45:18 47:15,25 48:14,19 49:5,15 55:11,11,25 56:1 108:3 120:12 124:18 128:4,16 128:18 129:6,14 130:2,5,8 135:1,4 135:15,17,24 136:3,4 137:1,4,7 137:15,23 141:2,9 159:4 160:16 175:3 202:7	203:10,16,17 204:22,24,25 212:20 213:5,13 213:24 genotoxicity 37:21 geo 134:24 geoffrey 4:3 getting 119:5 149:24 151:3 155:11 176:12 181:21 197:9 213:16 giselson 39:13,17 gisleson 3:12 7:6 170:24 171:1,2 180:14,22 181:12 181:16,20,22 190:13 198:13 199:23 215:9 218:25 229:7 give 10:11 11:22 14:4,21 37:4 38:6 51:4 59:4 64:17 108:8 136:19 140:25 144:3 158:25 178:22 179:16 180:12 182:15 185:18 given 17:22 85:8 108:5 128:11 153:9 214:14 219:15 225:17 233:9 gives 185:16 199:17 giving 28:19 35:15 139:8 glad 122:13 glass 197:4 global 80:22	glp 67:20 68:3,5,9 68:11,12,25 69:1,2 69:4 98:17,19 110:22 114:21 gmp 68:9,11,12,25 69:1,2 94:2 110:22 114:21 124:19 go 17:4 23:9,25 25:7,11 27:4 29:21 31:5 42:23 47:8 50:3 51:6,7 51:12,15,17,20 54:13 57:20 63:16 66:4 69:20 87:25 90:2 91:18,18 105:4 110:1 111:16 118:1,4 121:15 129:4 139:15 146:13 150:23 158:1 165:21 169:14 170:17 171:2 173:3 175:17 182:17 183:2 185:1 187:24 191:21 196:13 197:4,7,19 199:19 204:11 206:7 209:23 210:9 211:11 219:22 220:9 226:8 goal 123:20 149:12 168:22,22 192:6 god 113:5 goes 64:25 99:14 176:21 177:1 184:19 191:23 203:5,6 204:2 213:18 214:20
g			
g 63:13,13 ga 5:7 gannon 5:14 gas 175:18 177:16 185:10 gateway 5:14 gc 45:16 178:4 gcms 45:16 120:12 131:12 206:13 207:9 212:1,21 214:23 227:17 gcoan 4:5 gears 56:2 geigy 163:13 general 68:9,21,24 169:2 191:5 generally 205:5 generate 63:21 109:24 generated 63:16 64:2,23 75:23 76:2 113:24			

<p>going 9:2 15:7 17:10,11,12 24:25 29:24 31:6 32:8 35:22,24 36:19 40:2 41:4 42:20 50:3 51:23 56:2 57:15 59:15 68:15 69:23 72:11 74:13 74:23 78:23 79:1 79:15,25 96:5 107:6,7,11 119:20 125:8,20 133:1,8 134:2,8 150:5 151:10 152:13 164:20 168:22,23 169:14,25 170:7 170:16 180:16 185:10,11,12,13 186:4 187:3 189:22 197:6,17 198:9,10,11,13,23 199:21 203:14 212:6,10 213:17 220:12 221:12 223:4 good 9:1,14 10:18 10:20,21 32:16 67:25 68:4,13 71:22 91:23 92:2 111:7 117:1 141:5 170:25 174:24 175:3 178:24,25 179:4,22 187:8 188:10 196:5,6 201:25 206:7 209:3 229:11 google 25:16 122:11 124:13 132:1 145:21 150:6</p>	<p>gordon 3:3 gotta 187:10 gotten 112:12 governed 78:12 government 220:3 grant 3:6 141:15 great 40:12,19 greater 37:17 47:5 greenberg 5:4 gritty 197:10 ground 198:10 group 164:16 growing 186:16 gtlaw.com 5:8,8,9 guess 40:25 41:2,2 66:11 68:19 81:25 83:18 97:10 103:9 164:23 207:4 221:18 guidance 26:24 36:11,25 48:17 110:21,21,22 168:24 169:14 174:8 180:23 181:1,3 191:4 202:12 205:4 guidances 178:17 202:6 guideline 45:10 49:17 56:5 68:21 78:16,17 204:17 227:14 guidelines 55:10 55:11 68:5,6,20 69:5,16,18,23 77:25 78:4,11,13 137:25 178:18 203:13 204:12 212:21 213:3 guys 39:5 124:13 129:4 178:22</p>	<p>192:12 200:11 h h 63:13,13 232:3 half 95:10 163:18 halt 17:15 ham 201:3 hand 10:10 182:22 hands 83:7 hang 27:1 46:17 175:16 happen 112:19 happens 111:11 119:4 176:20 209:18 happy 141:8 harding 5:10 harkins 5:4 7:7 201:24 202:3 228:6 229:9 harkinss 5:8 harmful 12:17 14:9 15:17,18,20 21:1 36:1 harmless 11:19 12:6,13 13:2 14:9 15:17 21:2 202:21 hazard 183:17 hazardous 11:20 12:6,14,15 13:2 202:21 hct 163:9 head 67:7 127:18 133:14 health 12:17 183:16,17 192:17 219:17 220:6,8 222:19 healthcare 3:16 hear 16:10,12,13 35:15 141:10 142:11,13,14,15</p>	<p>154:15 202:1 211:16 214:10 heard 61:12 98:6 heart 193:25 heavily 94:2 held 1:18 62:23,24 hell 189:13 help 86:12,13 98:20 99:10,15,19 99:25 128:17 141:20 193:16 207:23 helping 100:5 122:21 henry 5:19 hereinbefore 230:11 hereto 233:7 hesitate 207:4 hetero 70:25 162:19 hey 174:17 hiding 188:9 high 55:7,13,15,22 55:25 117:15,16 120:12,20 134:21 135:14 141:1,1 176:3 193:8 200:7 201:19 higher 130:3 149:15 152:7 highest 32:18 highlight 105:7 157:23 222:14 highly 213:24 hill 3:19 hilton 2:4 39:12 78:3 223:1 hinshaw 4:3 hinshawlaw.com 4:5</p>
--	---	--	---

[hmm - impurity]

Page 19

hmm 140:5 147:6 158:8 195:13 202:23 hoffman 57:11 hold 21:15,15 22:12 24:21,21,21 26:13 28:16 37:3 40:5 41:2 51:8 52:12 57:15 69:14 86:19 87:7 93:2,5 93:8 99:2,5 102:6 102:6 149:18,18 149:18,19 155:7 190:10 212:5 holder 18:7,25 152:2 hollis 66:24 homework 49:22 honest 154:16 193:4 honestly 72:2 74:17 139:15 140:24 181:7 hope 30:13 32:21 32:22 192:7 hopefully 129:4 hoping 30:11 hospitalization 193:25 hour 102:24 hours 32:10 82:6 82:14 83:1,13,18 84:2,7 103:3 162:21,22 170:9 170:13,16 hplc 175:18 176:14,21 177:21 178:3 187:10,19 205:15 207:17,23 huahai 3:16	huge 160:20 204:5 huh 91:19 182:24 humana 4:15 humans 107:13 hunchuck 3:12 hundred 141:22 184:22,24 hundreds 137:11 159:10,11 206:2 208:25 hurt 193:16 hydramine 133:22 hydrochlorothia... 182:6 183:8,12,14 i i.e. 191:24 ich 45:10 49:17,17 55:10 56:5 69:19 137:24,25 178:18 179:15 202:10,20 203:12,14,14 205:5,6 213:3 idea 39:10 49:4 71:24 78:21 193:7 224:11 identical 31:11,25 31:25,25 32:1 35:11,13 identified 11:2 45:10,11 131:10 147:4 169:20,21 173:16 174:1,3,25 175:15,23 181:4 183:7,11 184:15 187:15 188:15 190:8 205:11 210:16 214:6 identify 28:7 37:9 37:13,16,18 38:13 38:15 43:21 44:2 56:19,22 110:23	110:24 131:12 173:12,21 175:10 175:12,17 177:15 179:19 183:6 184:17,25 185:5 188:21 196:18,24 206:23 207:13,14 207:19,20,21 208:4 213:5 identifying 177:11 187:19 205:17 209:5 226:11 227:25 identity 27:12 35:12 50:19 54:9 127:15 ignored 139:11 il 4:17 imagine 209:4 imd 99:11 immediately 93:21 impact 197:6 214:1 implementation 119:8 importance 113:11,17 important 47:6 112:24 113:2 improper 64:19 impurities 11:11 11:15,18,20,25 12:5,9,13,15,16,23 13:2,6,21 14:9 15:17,19 20:25 21:1,2,4 27:15,16 27:17,19,25 28:4,7 35:25 37:9,13,16 37:19,20,21 38:13 38:16 42:25 43:5 43:8,11,13,14,21	44:8,15,19 45:18 45:19 46:1,5,7,9,9 46:21,25 47:5,6,11 47:19 48:19 49:5 49:14 54:18 55:7 55:24 100:14,24 101:7,11 102:9 110:24 123:7 129:18,25 130:2,6 134:21 135:13,15 135:18,24 136:3,4 136:5 137:4 141:9 172:14 173:12,15 173:17,19,22,24 174:1,14,18,25 175:1,10,13,17,24 176:5 177:18 178:9,12,20 179:2 179:6 183:3,7,10 183:18,22 184:4 184:12,17,21,23 185:3 186:10,13 186:16,25 187:4,7 187:17 188:19,22 191:13,14 193:11 196:3 202:7,8,24 203:9,11 204:16 204:25 205:12,17 205:20,25 207:24 208:4 213:22,24 218:1 219:23 226:1,13,16 227:10,19 228:1 228:25 impurity 14:10 15:22 16:4,24 17:19,25 18:1,2 19:2,7,11,14,16,22 20:3,10,12,20,21 21:20 22:9 25:19 25:25 32:5 35:6,7
--	---	--	---

[impurity - interrupted]

Page 20

35:17,23,25 36:4,5 36:9,15,19,20,24 45:7 47:15,16 48:5,9 55:20,21 67:5 87:13 88:5 94:6,7 108:2,9 128:2,4,9,14,14,16 128:20 129:5,12 130:18 131:10,11 132:3 137:1 139:4 173:10,18,18 176:1,11 184:2,8 186:2,9,20,21,23 192:3 202:13,21 204:3,14 206:4,16 207:13,15,18,20 207:22 inactive 193:14 inadvertently 21:21 inappropriate 21:16 28:17,21,23 28:25 29:2,11,12 29:18 30:8 33:16 33:22 34:17 include 80:17,20 174:13 184:3 201:1 included 225:13 includes 113:23 225:16 226:11 including 50:18 54:9 95:19 96:4 113:24 114:10 154:10 201:3 207:4 income 63:21 increase 194:12 incubated 93:22 95:3 96:10,15 98:1,3,4	ind 155:1,1 independent 25:22 63:23 171:20 independently 141:25 143:7 166:22 index 7:1 india 136:21 indicate 9:25 53:7 104:25 indicated 79:8 80:6 119:14 136:8 136:23 216:19 individual 47:4 110:2 213:9 inds 97:7 industries 5:2 industry 209:19 211:2 inert 46:6 infallible 102:7 information 8:16 38:10 64:22 65:6 65:7 72:17 73:15 74:24 77:2,6 78:19 79:4 100:2 119:24 131:4,14 131:16,19 140:20 153:13,17,21,25 154:2 163:13 173:6 176:10 199:3,17 215:4,23 216:1 217:16 225:17,20 226:18 ingersoll 5:18 ingredient 18:5 127:16 ingredients 27:12 27:14,21 31:10,21 35:10 37:24 50:21 137:9 155:20	inhibits 194:2,11 initial 116:15,17 116:22 120:23 192:2 initially 73:8 116:1 initiated 73:5 innovators 172:8 inspected 68:11 98:19 114:20 inspection 108:24 109:16 111:4,18 112:5,22 118:22 119:17 inspections 109:8 109:10,12,15 inspector 111:18 instance 227:6,16 instances 201:9 instruct 39:6 57:16 59:16 60:6 61:8 73:16 78:24 79:16,25 81:6 151:10 199:6 213:17 instructed 39:15 80:25 instructing 76:4 instruction 13:12 64:17 80:3,9,22 81:5 instrument 175:19 176:14 207:2 instrumentation 45:16 175:19 instruments 110:2 207:2 insulted 144:22 intake 190:8,21 integrity 113:4	intend 88:11,20 89:3 138:18 intended 79:13 193:23 194:20 intending 68:8 intends 77:4 intent 102:11 intention 30:3,5 30:10 intentionally 21:21 interaction 193:8 interactions 93:24 interest 215:19 228:2 interested 21:11 85:3 119:25 230:16 interestingly 147:9 interferes 193:22 194:19 interim 149:2 167:12,12 168:21 169:13 191:2 192:4 217:11 interject 198:5 intermediates 27:22 internal 162:10 163:3 international 179:25 180:25 181:3 internet 16:9,11 interpret 134:23 135:22 interrupt 15:5,11 34:14 interrupted 14:25 34:3
---	---	---	--

[interrupting - know]

Page 21

interrupting 33:25	120:2 139:25	judgment 111:19	65:9 66:15 67:6
intubate 98:4	141:19 161:9	july 82:7	67:24 68:17 69:12
intubated 97:25	170:1 180:23	jump 140:9	71:3,7 72:2 73:20
98:6	182:3 196:20	jumping 220:11	73:20 74:1,7,8,10
invariably 197:23	209:7	june 44:21 45:4	74:11,12,15,16,17
invented 95:16	issued 104:13	115:15 131:4,15	74:17 75:1,2,13
investigation 97:7	111:5,17 112:13	143:23 144:9	76:19 77:5,7
investigator	119:18 179:20	178:8 179:1,20	78:16 79:3 81:3
111:18,25	181:1 210:8	215:11	82:25 83:4,21
invisible 177:8	issues 16:11 29:2	k	91:4,16 94:5,8,10
188:25	89:19 109:14	k 63:13	94:11,11 95:1,13
invited 108:8	110:3,6 112:6	kanner 2:3,7,7,8	99:18 109:5,21
invoice 8:6,7,8,9	118:20 139:12	kapke 4:12	112:9 113:3,5
82:2,5,14 83:9,24	160:13 162:22	kara 4:12	114:5 117:10,13
invoices 81:22,23	170:3 197:11	keep 29:24 30:4,5	117:14,18 119:6
84:20	198:14	39:16 64:17 90:19	119:18,19 120:3,4
involve 70:16,19	ives 4:16	90:21	120:18 121:12
70:24 71:5	j	kelly 63:9,14	123:17 124:21
involved 62:8	january 82:11	ketone 185:9	126:14 127:4,5
71:10 74:6,9,12,18	83:10	key 180:12 192:2	128:5,14,17 131:2
93:12 94:2 97:18	japan 95:20	227:22	131:3,22 133:20
154:25 155:5	jason 3:5	kidding 187:14	133:22 136:14,17
156:6,24 157:12	jdavis 2:19	kind 20:25 21:4	137:7,20 140:20
158:17,18 177:24	jersey 1:1,18 9:7	124:20 139:8	140:24 141:3,4
195:10 196:16	11:1 230:3,21	196:22	145:22 146:13
203:8 209:16,24	jmr 3:9	kinds 133:9	148:20,24,25
223:17,21 227:24	job 224:25	kkapke 4:14	149:1,3,19,22
involvement	john 2:17 3:12	knocks 189:13	151:2 152:13,25
141:15	39:13 171:1	know 13:16,17	152:25 153:12
involves 226:14	184:23 185:8	16:9 20:10 25:15	154:9,17,20 156:1
involving 11:1	189:9,23 190:25	26:14 32:7,9,13,14	158:17 159:3
62:7 227:24	193:4 197:20	32:15,25 34:25	161:3 162:23,24
irac 180:1	199:15 200:10	35:4,12,19,20 36:7	163:7 167:5,14
irbesartan 1:4	201:7	36:9,12,13,23 38:1	168:6,20 169:7
irrespective 20:24	john.gisleson 3:14	43:17,18,25 45:13	170:17 171:9,16
21:3	join 45:23	45:16,25 46:10,20	172:2,8,9 173:9
issuance 122:24	journal 100:23	46:22 47:4 48:13	174:3,7,18,22
issue 16:10 75:8	101:12 161:14	49:17 53:17 54:7	176:13,22,23
105:1 107:4	journals 101:4	54:8 55:12,25	177:21,23,25
111:11 112:6	judge 17:12 29:1	58:17 59:8,22	178:11,22 179:13
115:14,22 116:1	29:14,21 30:2,7,17	60:25 61:12 65:8	181:7 183:20

[know - limit]

Page 22

185:2,7,9,16,19 186:4,23 187:9,10 188:11 190:1 191:7 192:12 193:5,5,15,17,19 194:14 196:9 197:7,9,11,20,22 197:25 198:1 200:10 201:10,18 203:7,23,24 204:4 205:24 207:8 208:24 209:17 210:1,11 211:11 211:23 212:23 214:1,21 217:9 218:2,2,8 220:17 221:15 223:20 224:7 227:16,25 knowledge 166:21 167:18 171:11 178:6,11,15 183:16 194:17 217:3,5 known 49:14 110:25 174:14 178:13 191:11 198:3 219:24 knows 75:5 korea 95:19 ks 97:8	93:19,22,23 94:1 94:20 95:1,3,4,5,8 95:9,14,17 96:10 108:19,25 111:24 113:21 114:21 116:17 119:12 142:1,23,24 145:19 147:24 207:3 label 8:12,13 21:19 37:10,14 39:3 40:4 42:15 42:24 43:14,18 194:21 labeling 38:1,3,14 38:20,23 39:21 42:4,17 43:14,22 laboratories 3:2 laboratory 67:1 68:4,11,14 71:10 96:3 98:16 108:1 111:7 117:1 189:14 208:9 labs 68:22,24,25 93:2,5,8,11,15 94:16,24 95:12 117:1 laid 205:5,5 language 49:19 50:23 185:13 large 104:22 159:22 198:20 200:4 215:22 lasagna 158:21 latest 32:20 48:12 179:5 law 12:8 66:24 71:3 73:23,24 74:2,5 116:12 law.com 2:7,7,8	lawrence 208:9 lawsuit 58:11 59:13 182:3 lawyer 56:20 74:8 84:16,17 116:19 153:1 lawyers 39:17 56:20 59:14 86:7 86:12 153:4 194:15 lax 187:12 layman's 137:18 layne 2:4 40:16 84:19 lays 175:21 lc 176:8 188:5,16 188:24 lcms 45:16 132:14 132:15 187:10,14 207:9 227:17 leading 221:12,16 learned 112:22 lectures 108:5 led 31:2 94:8 122:14 163:13 left 96:13,14 182:22 legal 6:8 9:8,10 74:13 85:10 231:23 letter 8:15 192:16 206:9,10 letterhead 85:25 86:3 144:8 letters 112:13 level 55:15 137:1 152:7 167:12,12 168:21 169:13 185:23 186:14 191:3 192:6 201:10,12,14	202:20 216:8,12 218:12 levels 79:9 117:15 117:16 120:7,12 120:20 121:22 136:5,11 137:17 137:21,24,25 141:1 145:17,18 149:1,15,16 150:3 150:14 151:2,14 151:20,20,22,24 152:3,5 166:8 174:2 189:11 190:7,8,20,21 192:3,4 193:8 199:15 201:8,18 201:19 202:13 203:12,15 204:7 204:24 205:8 216:23 levin 2:9,13 levinlaw.com 2:12 231:2 lewis 3:11 4:7 lewisbrisois.com 4:10 lfsblaw.com 2:15 liability 1:4 85:13 197:10 198:8,9,14 198:22,24 199:11 199:12,18 212:10 213:16 library 206:14 license 230:20 lieu 9:20 life 203:25 light 120:7 limit 45:17 49:16 149:2 165:25 166:1 167:8 168:3 168:17 169:4,10
l			
l 1:16 63:13,13 230:2,19 l.hilton 2:7 la 2:6 lab 60:24 68:8,23 69:3 70:3,14,24 71:19 72:4,19,21 72:23 73:2,7 76:8 76:17 77:14 78:11 80:14 92:16,21,24			

191:13,14 limited 79:22 85:12 limits 46:21 80:23 88:17 129:23 137:8 139:4 166:7 168:13 190:21 203:18 line 51:7 97:11 144:5 199:5 220:16 232:4,7,10 232:13,16,19 link 40:16 lipitor 218:7 lips 142:12 liquid 132:14 176:3 177:10 lisinopril 203:23 list 43:8,11,13,17 43:21 90:11,12 101:5 165:13 166:12,12,16,17 174:19 listed 19:3 20:13 20:21 31:14,24 46:8 47:7 88:7 129:13 136:5 137:2,3 138:8,22 140:1,3 147:14 152:2 167:2,6,15 167:22 173:18 213:21 223:18,21 listen 11:22 listening 40:7 lists 47:9 literature 24:4 100:13,22 154:13 209:1 212:1 litigation 1:4 9:5 10:24 11:3 57:25 58:4,10 60:1,3,21	61:1,5 62:7 63:20 63:20,23 64:4,13 64:24 66:1,2 71:12,18 79:5,12 80:2,19,22 89:2 105:19 107:2 126:8,11,14 138:20 140:1,12 162:18 litigations 60:12 64:14 65:3 79:23 little 37:4 53:12 77:18 108:18 130:3 160:23 184:24 186:3,12 201:16 204:6 205:11,12,20 206:2,24 livermore 208:9 lives 98:20 122:17 122:21 living 32:19 llc 2:3 3:10,16 5:2 5:17 llp 2:13,16 3:4,11 3:18 4:3,7,16 5:4 5:13 6:3 localities 96:6 located 10:19 lockard 5:5 lockardv 5:8 log 110:3,8 long 17:11 28:9 32:21,23 91:7 92:21 99:21 129:6 129:14 141:3 186:13,14 189:6 189:18 190:7,19 longer 170:21 look 17:4 24:6 26:4,17,20,21 31:3	36:7 40:3,13 43:2 49:23 50:5,13 51:1,4,13,18 52:9 95:23 123:5 132:20 133:2,2,10 136:21 141:23 144:11 145:16 146:15 147:12 158:24 159:3,4 163:20 167:1 173:11 175:8 176:5 178:16 180:2,8 185:4,5,7 185:8,15 186:2 187:1 192:11 197:14,15 204:3 208:12 215:2,19 225:11 looked 22:5 48:12 52:23 53:2 103:14 133:17,17,19,20 133:21 136:18 163:15,15,17 looking 31:4 42:17 42:21,22 43:18 51:9,10,10 53:3 66:20 78:7 83:3 91:1 131:8 146:16 154:16 162:9,22 162:22 164:13 173:9 177:3 179:6 179:14,17 182:9 182:22 187:25 203:6,7 205:8 206:4,5 214:5 224:12 228:25 looks 65:17 66:4,5 82:2 84:6 133:6 183:9 192:16 losartan 1:3 9:5 105:12 231:4	232:1 233:1 lose 111:12 lost 39:25 86:21 196:22 lot 26:2 68:24 83:20 94:6 108:1 116:13 121:20 123:1,11,19 124:7 124:16 136:4,20 139:8 150:10,23 152:18,20 153:7 153:10,12 154:8 155:23 161:3 163:11,17,18 180:4 188:23 193:11,12 197:25 209:16,18 225:16 lotman 3:18 lots 72:7 146:23 158:18 159:21 186:12 204:6 love 30:1,17 low 55:12 200:6,8 201:9,12,14,18 203:12,15 lower 136:3 166:2 193:1 204:25 205:1 lowering 193:24 218:8
m			
m 3:5 4:3 5:4 m7 45:10 49:17 56:5 137:25 178:18 179:15 203:14,14 205:5,6 ma 4:4 machine 207:18 magistrate 17:12 magnesium 193:13			

[mail - means]

Page 24

mail 39:4	175:5 176:11	226:22,25 227:3,5	materials 153:9
maintain 68:13	177:16 179:2	227:6,20,21	160:5 219:15
90:12	184:16 185:4	manuscript	matter 1:14 26:25
maintenance	186:9,18 187:6,16	101:10,15 102:9	57:24 88:11
112:3	188:18 196:18,19	102:21 103:10,21	101:20 107:8
major 94:8 95:17	196:23 199:6	104:25	129:8 158:11
majority 170:11	200:6,8 213:12	map 53:11	203:18
making 47:14	215:21,22 217:6	mark 166:17	matters 56:13,16
75:10 109:21	manufacturer's	marked 39:20	60:4,7,22 61:15
112:18 113:4	71:13 200:5,12	40:18 42:17,24	62:7
123:19 124:7	manufacturers	53:6,6 54:14	maximum 55:5
125:14 136:10	18:10 23:8,12,19	81:23 83:25 84:21	maz 4:18
179:6 203:7	23:24 27:9,18	85:15 89:24 90:7	mazzotti 5:10
226:17 227:20,21	30:22 31:7,9,18,20	91:5,24 101:6	mckesson 6:2
managed 45:13	37:16,18,23 38:13	104:11 115:18	md 1:7
management	38:15 58:5,13,15	118:4 143:24	mdl 1:2 56:10
110:7 111:11	58:18 59:5,9 72:3	164:23 181:18	57:14,22 58:19
112:3,8,23 113:4	72:22 80:21	220:12,13,21,23	59:10,12,14 60:2,3
managements	108:10 117:25	223:8	74:6,9,18 75:2,4
112:19	126:18 127:10	market 93:25	80:10 81:8,9,19
mandate 19:11	137:19 147:3,10	110:5 111:2	85:5
135:23	149:13 154:9	124:17 154:23	mean 15:12 38:1
mandating 25:18	156:14 157:17	171:24 186:18	82:20 103:1 114:2
manner 9:24	163:3 172:19	192:5	122:6,20 124:13
101:8 104:8	179:21 180:2,4,6	marketed 22:24	127:11 141:12
manufacture	188:12 206:11	23:4 165:13	150:18 172:3
92:25 93:13,16	215:5,11,17	markets 96:19	178:13 184:10
94:18,21 95:18	227:10	martin 5:10	199:19 215:21
96:24,25 98:23	manufactures	mass 176:25	223:16
110:14,17,19	95:14	177:16,21 178:2,3	meaning 31:19
126:20	manufacturing	178:4	176:3 191:15
manufactured	32:17 54:3 68:1	master 93:9	means 31:24 32:17
71:6 93:24 127:25	71:24 94:3 97:15	107:17,20 159:25	48:6 54:3 68:13
manufacturer	127:4 153:12,13	master's 92:3	68:14 82:25 111:1
18:22,25 19:14,20	153:15 154:11	match 19:11,14	119:9 129:23
20:1,19,23 37:9,13	159:16,21 160:19	20:13 25:19 128:2	130:12 148:13
43:13,21 72:16	160:21 162:22	128:10,15	176:2 184:11
73:25 81:3 107:23	171:13,15 178:24	matches 20:21	186:12 187:10
110:18,19 130:16	178:25 179:4,22	material 52:7 61:7	188:7 208:8 212:1
139:3 156:10	187:9 188:10	163:11	223:17
158:7,16 162:18	206:8 226:11,17		

[meant - misunderstanding]

Page 25

meant 148:4 184:7	menaski 17:13	161:16 177:25	144:1 163:22
measure 192:2	29:1	208:1,15,18,23,25	204:13
measured 45:15	mention 43:4	208:25 209:5,11	minutes 65:9 89:9
measures 113:1	49:13 143:12,13	209:15,18,22	131:11 134:3
mechanisms 116:7	145:20,23 146:7	210:1,3,7,9,11,14	219:2
media 9:3 41:8,14	150:18 151:1	210:16,16,25	mirror 19:11
89:11,16 118:12	179:11	211:1,3,5,7,18,23	25:19
118:17 163:25	mentioned 12:4,12	211:25 212:9,14	misbranded 11:14
164:5 219:4,9	47:16 48:6 57:7	214:19,20 226:15	11:24 12:8,14,18
medical 69:19	105:21 116:3	227:11	14:11,13 15:18,19
106:5,6,23 107:5	121:22 131:24	methyl 67:8,9	15:23 16:5,25
131:21	143:4 146:5	methyldating 168:8	17:20 18:2,3
medication 80:15	148:10 165:17	168:8	41:21,24 42:4,8,14
224:8,9	179:15 188:11	michelle 1:16 9:9	216:13,25 217:18
medications 70:4	190:25 202:6	9:13,15 16:15	217:22,25 218:13
70:17,25 71:11,20	205:11 211:20	45:22 230:2,19	228:7,19
72:5 80:18,20	213:3	mid 108:16	mischaracterizes
93:18 138:19	mentions 178:18	middle 14:25	50:8 190:11,24
166:23	mere 14:10 15:22	15:11,12	misabeled 21:19
medicine 50:20	16:3,24 17:19,25	miller 6:8 9:7	misleading 42:5
54:8	128:19,24 129:2,5	milligram 54:24	42:15 217:23,24
medicines 50:18	merely 12:8	55:8,22 134:22	218:3,18
225:25	meridian 4:13	135:14	mispronounce
medium 200:7	merit 79:12	milliliter 165:20	144:23
meet 20:19 22:24	met 204:15	169:6	misquote 191:20
23:5,11,13,19	metformin 59:14	millimeter 168:16	misrepresented
50:21 55:17 98:16	59:21 60:1 126:11	million 54:21	53:16,18
138:10 172:17	method 120:22	137:11,12 205:2,2	missed 207:16
173:2 174:2	121:5,9 132:14,16	mind 63:10 118:6	210:25 212:2
202:24 203:12	187:5,15,18	142:3	215:20
meeting 45:23	207:18 208:24	minimum 23:7,8	missing 91:9
167:1	209:2,3,15,20,20	23:24 24:3 25:6	170:20
meetings 99:12	227:18	32:15 50:5,16	mission 97:21
156:20	methodologies	51:3 53:1,8,22	98:14,20,25
meets 161:19	125:11,13 137:18	54:4,12 55:5	122:17,20
megan 4:16	methodology	172:17 173:2	misspoke 135:19
members 104:3	126:1 132:13	201:10	misstate 141:12
memory 84:4	175:12,14	minor 197:19	mistake 179:11
102:7 124:12	methods 114:18	minute 33:4 56:3	mistaken 122:10
143:15	120:25 121:1,23	89:7 118:2,2,7,9	misunderstanding
	131:3 132:7	118:10 134:6	214:4

[mitchell - ndma]

Page 26

mitchell 2:9 mixing 122:11 mm 140:5 147:6 158:8 195:13 202:23 mode 176:8 188:5 188:16 modified 127:6 modifying 28:1,3 28:5 mods 210:13 molecular 32:1 206:17 molecule 94:11 133:3,4 137:16 185:8,11 193:7 197:15,24 molecules 158:25 159:10,11,22 189:12 206:15 214:15 mom 120:14 203:21 moment 144:3 215:10 monitor 42:19 129:24 monogram 193:12 monograph 22:23 23:1,3,6,12,14,18 23:20,24 24:3 25:5 46:2,20 47:19 48:3 50:17 53:4,25 54:1,13 130:5,10 171:4 173:8,21 174:23 175:9,11,15,23 177:15,20 179:9 181:13 182:6,10 182:19 184:15 187:6,16 210:1	monographs 50:15 52:25 53:7 53:21 171:6,12,14 171:17 172:1,5,23 172:24 173:5 174:9,13 182:2 195:8 monroe 4:17 months 109:7 162:15 morgan 3:11 morganlewis.com 3:14,15 morning 9:1,15 10:19,19,20,21 morris 3:18 mother 141:5,6,7 motion 170:1 move 16:18 28:12 29:10 81:15 moving 30:5,14 142:12 mulberry 5:15 multipage 50:25 multiple 24:7 93:23 190:12 211:3 mutagen 178:20 mutagenic 87:9 88:15 96:4,5 189:12 mute 9:13 mylan 3:2,2,2,2 70:4,10 71:20 117:24 150:13,19 162:10,14 216:2 221:5,5 222:1	195:12 n.v. 3:2 najafi 1:9 7:3 8:4 8:10 9:4 10:8,9 33:17 39:14,15 40:17 48:20 51:9 52:20 62:13,15,16 62:18,21 63:15 66:25 75:1 155:7 168:10 201:25 210:15 211:4,6 212:16 213:19 218:19 223:12 227:8 230:5 231:5 232:2,24 233:2,4 233:12 najafi's 162:3 name 9:7,15 10:1 10:7,8,22 18:19 57:4 62:17 63:8 63:13 65:5 71:14 85:22 116:4 126:5 144:25 145:20,23 146:6,7 148:9,12 148:13 156:5 170:25 202:3 221:9,21,23 222:5 222:20 223:14 224:8,10 named 1:13 names 57:1 144:23 155:19,24,25 nanogram 222:10 222:11 nanograms 54:25 54:25 55:7,14,23 56:1 117:17 134:22 135:14 149:3,5,17 150:3 150:14 151:15 165:19,23 166:8,8	167:13 168:16,21 169:5,7,10 189:6,7 189:19,20 191:2 224:22,23 225:1,3 225:6,8 nap 180:5,8 narrow 196:14 nature 12:15 nbma 67:2,4,6 nc 5:20 nda 99:11 154:5 154:18 155:2 195:22 209:21 ndas 100:5 ndea 48:1 67:2 79:20,21 86:17 87:5,8 88:15 106:21 107:12,15 120:21 138:2,6,8 138:24 140:4 145:6 149:9,13,15 150:13 151:23 152:1,6 165:25 166:1,2,9,13,18 167:7,13,15,18,23 167:25 168:2,5 169:10 189:3,7,11 189:20,23,24 192:25 193:8,9,22 194:7,10,19 198:18 200:16 206:23 207:21 208:12 209:6 210:17 211:3 213:22 216:8,12 222:11,17,20 224:16 ndl 9:7 ndma 48:1 67:2 79:18,18,20,21 86:17 87:5,8
---	--	--	--

[ndma - nitrate]

Page 27

88:15 101:14	necessity 123:16	154:22 156:6,22	101:24 102:14,23
106:17 107:12,15	need 27:12,14,15	156:23 157:4,5,7	103:3,11 115:1,23
117:16 120:7,12	29:14,20 34:21	157:10 163:6,8	115:25 118:8
120:20 124:18	35:10,11,20 40:10	174:25 195:23	121:8 126:6
129:22,23,23	41:3 43:24,25	226:14 227:17,24	128:23 129:1
130:8,15,23 131:7	44:1,2 45:10,11,12	230:3,21	131:5,17,20
131:12 133:4,9,11	45:12,16,21 75:8	newark 5:15	132:10 134:5
136:7,17,18,19,22	81:10 85:17 90:3	newest 227:16	135:2,5,16 136:1
137:19,22 138:2,6	112:6,11 114:11	news 61:21 131:25	136:13 137:5
138:8,9,12,23	133:24,25 134:3	132:4	139:1 142:14
139:12 140:4	137:8 139:7 157:1	nexus 79:5 81:9	146:14 147:25
145:17 146:3,5,9	159:1,2 174:1,3,3	nigh 2:10 7:9 10:4	148:2 149:18,23
147:16,23 148:16	174:17 179:14	10:4 11:16 12:2	150:16,22 151:10
149:2,9,13,15	182:14 185:20,20	12:10,20 13:7,14	151:17 154:19
151:23 152:1,5,8	186:15,20 187:8	13:23 14:14,24	155:7,10 163:22
152:11,15 165:19	196:11,13 197:5,8	15:4,10,24 16:6,14	165:21 168:10,19
166:8 167:7,15,18	198:5 203:9,11	17:1,21 18:8,16	170:7 172:6,20,25
167:23,25 168:2,4	204:1,2,20 205:24	19:4 21:7,15	173:7,23 177:19
168:7,17 169:5	206:3,6,22 208:11	22:12,18 23:21	178:10 179:24
178:15,16 180:10	208:24 215:19	24:21 25:20 26:13	180:13 181:20,24
181:2 189:3,7,11	227:23	28:16 29:6,10,16	183:19 184:5
189:14,19,23,24	needs 35:13 83:7	29:22,24 30:3,13	189:8,21 190:10
192:24 193:8,9,21	99:19 111:14	33:12,20,25 34:13	190:15,23 193:3
194:19 198:2,4,18	113:24,25 114:6,7	34:16 37:3 40:2	198:5,20 199:10
199:15 200:15	202:13,21 227:18	41:22 42:1,7,13	199:16 200:2
206:23 208:12	neighboring 96:6	43:3,9,15,23 44:10	203:2 204:18
209:1,3,6,15	neither 230:12,15	44:12,17,25 45:8	208:5,22 209:13
210:17 211:1,25	never 33:8 97:22	46:3 47:2,12,21	210:5,19 211:9,15
213:22 214:16,20	97:23 123:14	48:11,21,25 49:7,9	211:17,21 212:5
214:22 215:18,20	131:19 156:17	49:11 50:1,7 51:8	213:15 214:9,12
216:8,12,20,23,25	158:12 160:13	51:17 52:19 53:9	216:3,15 217:20
217:8,10,17 218:6	192:21 210:2	53:15,18 55:3,9	219:1,11 220:13
218:10,10,12	211:7	57:3,4,15,19 59:15	220:17,22,24
222:10,17,19	new 1:1,18 2:6	59:19,25 60:6,11	221:15,20 222:22
223:25 224:19,22	5:11 9:6 10:25	60:16 61:4,11	223:6 228:3 229:2
224:24 225:1,3,7,8	93:2 97:3,6,7 99:2	64:7,12,25 73:14	229:10 231:1
ndms 224:19	99:6,17,17,25,25	74:22 75:19,24	night 229:11
ne 5:6	108:7 126:24	76:3,6,11,19 77:17	nine 45:14
necessary 99:12	127:1,2 129:10	77:23 78:23 79:15	ninety 165:23
170:21 200:4	152:16,21 153:4	80:8 81:2,16	nitrate 197:24
233:6	153:16,20,24	85:10 89:8 101:1	

[nitrated - objections]

Page 28

nitrated 198:1	200:22 201:1,6,8	131:1,3,7,14,24	objected 85:11
nitrite 185:11	205:3 215:14	132:2,2 136:12,18	151:8
197:21,22,24	228:1	136:18,20 147:10	objecting 222:3
198:3 215:19	nitroso 88:16	147:13,17,22	objection 11:16
nitrosamine 8:19	137:13	148:15 149:5	12:2,10,20 13:11
44:23 45:6 60:3	nitrosol 67:8	152:2,3,7 153:2,16	13:14,23 14:14
63:20 64:3,23	nitty 197:10	154:10,11 216:19	16:6 18:8,16 19:4
65:3 67:5,9 74:11	nizatidine 133:18	216:23,24 217:5	22:18 23:21 24:22
79:9 80:15 87:13	nj 5:15	221:1 223:24	25:20 26:13 37:3
88:5 100:14,24	nm 176:9	224:7,8,11,16	37:5,6 41:22 42:1
101:3,7,11 102:9	nmt 184:1	novel 24:18	42:7,13 43:3,9,15
103:19 117:11	noise 123:19 124:8	november 82:16	43:23 44:12,17,25
121:5 130:18,19	non 36:21 130:2	83:15,15 222:13	45:8 46:3 47:2,12
131:14 132:2,13	134:24 135:3,15	number 8:2 11:10	47:21 48:11 49:7
136:11 137:14	135:17	58:23 64:5 117:24	49:9 50:1,7 53:9
140:11 142:5,19	nonexistent	127:12,12 160:20	53:14 55:3,9
143:9 160:18	130:12,14	182:4 191:8	59:15 60:18 77:13
177:17 178:2,9,12	nonresponsive	217:11 222:25	85:12 101:1 115:1
178:17,19 179:2	28:13,19 30:6,14	223:2	115:23 121:8
180:8,9,10 181:2	norris 6:3	numbered 143:24	126:6 128:23
185:14 188:22,24	norton 6:3	164:25	132:10 135:2,5,16
190:7,20 191:18	nortonrosefulbri...	numbers 48:18	136:1,13 137:5
198:2,3 201:11,15	6:5	64:10 71:22	139:1 146:14
201:16,19 208:16	notary 1:18 230:2	137:10,10 142:9	147:25 148:3
209:7 210:10	230:21 233:13,19	142:20 150:9	149:19 154:19
212:17,19 226:1	note 231:10	167:18	165:21 172:6,20
228:24	notebooks 68:14	numerous 213:9	172:25 173:7,23
nitrosamines 58:6	noted 9:11 233:7	ny 5:11	177:19 178:10
58:14,20 60:23	notes 160:3 163:20	o	179:24 183:19
61:2 62:7 78:15	notice 102:17,18	o 185:8	184:5 189:8,21
101:14 102:20	149:4 160:9	o'reilly 5:13	190:10,11,23
105:1,13 115:21	notification	oai 119:12,13	193:3 200:2 203:2
117:16 129:16	130:19	oath 9:21,22 72:14	204:18 208:5,22
132:7,23 134:17	novabay 93:20,23	154:4 156:5	209:13 210:5,19
136:6,16 137:13	94:24 95:3,3 96:9	object 17:21 21:15	211:9,17,21 212:6
141:19 160:16	96:10,14,16,17,22	24:22 28:12,18	213:15 214:9
161:7,9 168:24	97:1,2,11,17	47:22 48:21,22	216:15 217:20
177:6,7,12,14	159:24	64:8 74:23 78:23	221:12,19 224:25
178:14 179:22	novartis 42:25	168:19 216:3	225:10 226:20
180:3 191:23	43:4 124:18,24	221:16,16 225:4	objections 9:23
193:14 200:16,19	125:3,6 130:25	227:12	77:10 103:4

[objections - package]

Page 29

170:12 obligation 28:6 30:22 126:4 observed 166:7 observes 111:19 obstructionist 17:13 obtain 108:20 109:4 154:23 170:1 obtained 92:3 obvious 215:1 obviously 79:13 103:16 123:17 133:17 136:18 167:10 occurred 41:11 52:1 89:14 118:15 134:11 164:3 180:19 198:21 219:7 october 56:18,18 66:5 70:2 71:18 82:15,16,18,21 84:24 odor 196:8,9 offer 56:10 60:5 77:4 88:4,11,20,21 89:3 113:13 138:18 151:19,21 192:20 offered 24:18 136:24 139:22 169:24 228:11,16 offering 107:8,11 107:14 228:11,14 228:17,20 office 40:6 143:21 157:9 official 119:14 120:4,24 149:4	195:5 officially 96:11 110:23 140:15 oh 185:12 okay 11:8,9 16:21 27:1,7 29:22 30:13 31:5,6,7 38:11,17 39:9,22 42:16 43:2 46:14 47:13 51:14 52:5 52:8,24 70:20 79:6 81:23 82:1 83:9,24 87:22 89:25 90:25 91:19 91:22 105:6 111:3 118:10 123:14 128:13,19 138:1,2 140:8,19 141:23 142:16,18 143:4 144:6,20 146:13 147:2,11 149:23 167:5 180:14 181:24,24 182:14 182:14,17,21 183:5 186:2 202:1 215:21 218:7 219:1 220:9 222:8 223:11,23 224:15 228:21 229:11 old 217:5 once 203:24 214:13 ones 208:1 221:4 ongoing 27:9 31:8 31:18 79:10 80:7 online 51:11,12,18 108:12 150:11 179:13 open 39:5,6,8,9,15 110:1 119:1,10,11 181:9,15	opening 199:20 opens 179:10 operate 62:12 98:10 206:14 operates 80:13 operating 114:16 operators 71:23 opinion 25:1 57:20 59:20 60:8,12 61:4,14,19,20 62:9 79:17,18 85:12 86:19 87:6,11 88:4,18 107:14,15 111:25 134:16 136:20,24 137:21 138:4,5,17 139:9 139:22 140:2 147:22 151:19,21 151:22 168:4 188:7 189:1,16,25 190:1,4,17 191:1 193:4 213:18,19 216:8,11,24 217:8 217:17,21 218:13 228:14,20 opinions 60:21 61:23 62:2 77:3,6 86:15,24 88:10,19 88:21,24 89:2,3 107:8,12 125:12 125:14 139:24 162:8,25 198:8,10 199:13 212:13 228:11,17 opportunity 30:18 77:7 143:7 oral 1:13 order 73:21 108:20 227:9 ordered 67:19 69:22	organic 92:4,8 185:24,25 organization 98:20 180:25 original 197:21 orleans 2:6 ought 75:12 outdated 227:11 outlining 107:22 114:17 outside 11:16 12:2 12:10,20 13:8 14:14 17:1 18:16 19:4 21:7 22:18 24:25 50:7 64:25 76:22 80:1 96:3 103:4,8 114:1 131:5,17,20 132:10 150:16,23 150:24 151:4,12 151:18 170:10 199:13 201:18 210:14 213:18 216:3,15 217:20 oversight 159:15 159:18 overview 25:5 53:4 owns 63:5 95:10 oxford 3:6,13
p			
p 2:1,1 3:1,1 4:1,1 5:1,1 6:1,1 180:5 p.a. 2:9 p.c. 5:18 p.m. 229:14 pa 2:14 3:7,13,20 4:9 pacific 1:20 9:2 package 83:6 209:21			

[page - pharmaceutical]

Page 30

<p>page 7:2 8:2 47:8 49:18 50:11 53:2 54:16 66:4,20 90:2 91:15,17 105:4 146:16,17 146:17,20 147:12 150:25 157:25 165:6 176:6 182:23 183:4 187:20,24 191:7,8 192:14 198:7 219:21,21 220:9 220:11 222:9 223:11 226:5 228:25 232:4,7,10 232:13,16,19 pages 53:6 90:18 90:22 91:21 225:14 paid 63:22,25 64:3 66:15 143:13 papantonio 2:9 papers 160:7,11 160:24 paragraph 28:10 33:5,7 34:20 66:21 67:16 105:8 121:16,17 125:8 125:22 191:8,8 226:9 paragraphs 144:12 parameters 129:10 pardon 185:12 park 5:11 part 38:19 44:6 48:5,25 53:10 56:7 59:6,9 67:10 67:12,15 76:14 112:8 113:3</p>	<p>116:21 119:21 121:16 122:16,23 131:23 150:8 153:16 160:14 165:9 179:22 180:1 191:6,9 192:11,18,22 193:20 194:23 198:20 205:1 209:21 219:14 223:14 participate 99:12 participating 9:16 particular 43:5 45:1 47:9 69:7,8 125:10 particularly 88:15 parties 9:22 74:25 80:21 230:14 parts 54:21 91:9 111:8 132:7 137:10,11 205:2 party 142:22,24 pass 178:22 passed 141:7 patent 127:14 172:12 patented 95:14,17 patents 154:12 163:15 path 19:19 212:10 pathologist 105:24 106:1,2,4 pathway 225:24 patients 38:11 106:24 189:17 190:6,19 paul 181:23 pay 72:2 peak 204:5</p>	<p>peaks 184:24 204:6 205:12,16 206:2,24 peer 100:13,19,23 101:3,12 106:16 106:20 161:8,11 161:13,20,23 162:4,6 pending 10:24 75:16 77:9 pendley 57:10 pensacola 2:11 people 119:16 160:21 170:5 188:12 200:25 205:24 211:2 218:2 percent 47:5,11,19 54:18,20 60:25 63:6 95:9 96:8 123:12 129:19 130:1,3 141:22 160:18 184:2,8,13 184:13 186:8,11 186:15 204:8,8 percentage 37:17 64:8 percentages 183:24 perform 68:12 193:23 199:6 213:12 performance 50:19 54:10 214:2 performed 67:20 69:23 196:19,25 period 87:10 105:14 151:23 168:1 169:1 191:19</p>	<p>permissible 169:5 permits 129:9 permitted 14:20 permitting 189:4 person 9:21 57:6 65:5 196:6 personal 86:3 158:12 personally 86:6,8 94:12 100:10 160:2 pertains 82:22 petition 100:16,21 104:4,7 121:20,25 122:3,12,25 123:12,13,15,22 123:23 124:2,9,14 143:14,17,23 145:8 148:10,17 160:17 161:19,22 161:25 162:1,2 222:23 223:8,9,19 224:15 pharma 3:10,10 3:10 5:3 8:5 62:13 62:15,16,18,19,21 63:15,24 64:2,23 67:1 68:10 86:1 96:14,15 97:25 98:9,15,18,22,24 98:25 99:2,5,8,21 104:13 105:11 106:11 110:14 111:5 118:22 122:7,17 123:20 125:14 171:9 223:13 pharma's 108:19 112:16 122:20 pharmaceutical 3:16,17 5:2 14:12</p>
---	--	--	--

[pharmaceutical - prescribers]

Page 31

18:5 92:12 93:20 94:1 96:8 97:16 125:15,21 127:16 127:25 128:11 130:22 133:3 136:25 137:9 155:20 179:3,21 pharmaceuticals 3:2 4:2,6 5:2 70:5 93:21 94:25 100:14,25 101:8 102:10 105:2 159:24 221:1 pharmaco 194:10 194:11 pharmacy 4:11 116:2 phase 176:20 phd 7:3 9:4 92:8 92:10 231:5 232:2 232:24 233:2,4,12 phds 94:9 philadelphia 2:14 3:20 phone 56:23 phrase 194:25 215:1 physically 9:17 physician 26:3 161:18 193:18 pick 132:25 picking 185:1 piece 39:4 121:3 piedmont 5:6 pietragallo 3:3 pietragallo.com 3:8,8,9 pills 67:18 69:22 71:22,25 76:21 116:9 120:18 140:23,24 142:20	142:21 146:23 152:6 224:16 piqued 110:10 pittsburgh 3:7,13 pizzi 5:13 place 43:10 78:5 78:11 109:9 151:1 151:19 230:11 places 108:12 plaintiff 73:25 80:24 228:5 plaintiff's 56:19 57:13,22 75:3 84:16,18 153:1,3 plaintiffs 2:2 10:5 58:19 59:14 60:20 64:3 66:1 74:3 127:3 194:15 plan 163:1 194:23 planet 13:1,5 14:8 15:16 planned 146:8 planning 142:25 plastic 197:5 please 9:12,25 10:7,10 11:23 15:10 16:23 20:17 24:10,11,15 30:19 34:14 38:2 41:16 46:13 56:14 57:1 65:15 86:21 90:2 90:4 103:24 105:8 105:25 110:20 113:15 144:7 146:10 157:2,22 163:20 171:3 181:16 183:3 187:24 191:21 192:15 210:21 plenty 154:13	point 46:23 50:12 51:9 53:24 54:8 75:17 77:10 79:1 87:15,17,18 97:24 114:16 150:18,24 151:3,5,6,11 170:8 173:9 174:6,7 179:8 186:6 188:17 198:9,15 206:16 213:16 points 11:8 policies 114:17 policy 53:4 political 189:25 pollution 96:2 portion 85:7 157:10 position 17:19 80:11 81:1 145:11 152:5 167:25 170:8,22 216:17 218:16 positive 104:7 possibility 167:22 possible 19:6 206:18 post 72:9 181:5 posted 25:13 potency 31:12 32:6,6 35:13 potent 191:11 potential 31:23 37:19 38:25 103:16 115:22 130:19 141:19 159:3 198:1 204:24 212:20 213:5,13 214:6 215:13 potentially 46:8 96:4 178:1 184:12	218:1 poulence 159:23 practice 1:16 174:25 175:3 178:25 practices 32:17 68:1,4 111:7 117:2 178:24 179:5,23 187:9 188:11 191:24 206:8 pre 37:22 70:20 71:9 181:5,6 predetermined 37:22 predicate 61:10 predict 227:25 predicted 37:22 predictive 226:14 227:22,24 prefilled 197:7,8 premarked 8:1 39:2,2 40:9 46:13 65:15 164:17 premises 113:9 preparation 83:22 195:11 prepare 97:3,5 100:5 122:24 155:14 prepared 86:7,7,8 99:8 121:13,14 140:25 154:22 159:25 160:7,24 166:25 preparing 83:22 84:9,11,12 100:9 104:25 155:5 prerogative 168:4 prescribers 38:10
--	---	--	---

[prescribing - production]

Page 32

prescribing 38:10 prescription 172:23 presence 14:10 15:22 16:3,24 17:19,25 58:6,13 87:13 88:5 175:24 177:17 191:16 192:24 196:3 213:21 215:13 226:12 present 6:8 9:18 27:15 86:18 87:6 87:9 183:23 presentation 108:9,10 179:12 presented 160:19 170:12 presenting 148:8 179:12 preservation 112:23 113:12,18 113:23 preserve 122:18 president 120:6 press 104:12,15,17 124:16 142:25 pressure 176:3 193:1,24 presume 63:5 140:9 presuppose 48:18 49:4 presupposes 47:24 48:1,14 pretty 17:18 34:16 67:24 142:10 227:13 prevent 128:17 191:16	preventing 226:12 prevents 95:25 96:2,3 preview 139:14 previewed 100:16 previous 16:19 56:7 159:22 189:10 previously 13:8 28:20 54:14 98:14 174:14 182:11 204:20,23 primarily 73:5 82:23 85:1 109:21 110:7 113:3 123:3 124:17 132:16 172:7 principle 175:20 princeton 3:16 print 40:10,12 prior 44:21 45:4 70:1,7,13,15 71:5 71:14 72:8 94:1 115:21 130:18 131:3,6,15 136:9 152:12 161:16 178:8 187:20,24 210:25 211:19,23 215:6,11 229:6 230:4 privately 62:23,24 privilege 60:18 73:17,22 75:14 76:25 78:24 103:17 privileged 60:9 61:7 71:2 73:15 73:18 74:24 75:20 75:24 76:3,11,18 76:23 77:16 79:3 79:5,25 115:5,12	pro 123:6,9,10,13 probably 55:16 59:7 92:22 96:11 99:14 108:16 109:6 120:17 132:22 207:9 probative 81:13 probial 97:13 problem 94:6,8 104:5 112:5 123:21 134:5 159:1,4 182:16 problems 123:7 procedurally 110:7 procedure 1:16 18:10,12,22 27:20 28:1,3 35:21,24 36:17,18 78:17 139:5 152:14 159:13 184:16 procedures 28:5 76:18 78:14 114:17 142:8 154:10,11,12 163:16 proceed 52:3 89:16 118:17 158:4 164:5 proceedings 77:4 process 18:6,14,24 20:24 112:18 119:3,7,9 152:14 153:14 158:21 159:7,9 197:3,12 197:21,23 processed 201:1 processes 159:11 226:11,18,23,25 227:21,22	processor 206:12 proctor 2:9 produce 46:4 produced 14:8,12 15:16 70:4,9,17,25 71:11,20 80:18,20 102:13 152:15 produces 96:17 producing 18:14 128:8 186:20 product 11:18,24 12:5,7,12,16,25 13:4,19 14:7,11 15:15,23 19:23 20:4 21:6,13,24 23:4,18 25:18 27:10 31:8 43:1,6 44:9,16 55:6,22 72:15 87:14 88:6 88:6 93:24 94:3 95:14,15,17,17,22 96:2 97:4,12 110:17 112:25,25 113:1 127:21 128:9 131:8 134:17,23 135:14 136:10,25 147:3 147:13 149:6,8,10 154:24 156:5 159:17,20 166:17 167:8 168:1 169:1 171:10 173:13 183:23 191:18 192:1 196:20 200:15 215:24 216:2,9,11,20,23 216:25 217:7,18 218:11,11,13,17 production 93:17 94:18 96:24
--	---	--	--

[products - qualified]

Page 33

products 1:4 6:2 11:11 12:18 21:8 21:9,18,18 31:19 44:3 58:7,20 68:15 71:6 73:6 79:18,19 92:25 93:13,25 96:18,21 97:13 98:23 110:5 110:13,15 112:10 114:19 127:6,9,12 127:14 128:1 138:23 150:15 152:1,12 155:3 161:9 164:10 165:7,13,18 166:6 166:13 167:6,19 172:24 179:3 182:2 189:2,5,18 190:6,18 192:25 193:2 215:12,13 217:15 219:24 proffered 103:5 profile 19:3,7,12 20:10,20,21 25:19 35:20,23,25 36:12 36:16,19 47:15 48:5 128:4,9,14,15 128:16,20 129:5 129:13 173:10 176:1 profiles 19:22 20:3 20:13 32:5 36:20 128:2 program 113:4 project 84:23 promise 204:10 promises 68:18 promotes 194:3,10 prompted 119:22 prone 133:4 180:7	pronouncement 50:4 pronouncing 18:18 proper 21:19 53:13 64:17 107:17 123:6 158:24 159:2 197:17 properly 32:8 proposal 8:5 67:11 67:12 proposition 24:2 24:18 proprietary 153:3 protection 159:1 protocol 76:13 114:17,24 115:3 117:3 172:13 protocols 76:8,17 77:14 78:11 proves 42:5 provide 26:10 48:9 60:22 98:16 101:22 115:2 160:4 175:11 177:21 provided 38:10 42:11 44:19 85:11 89:23 105:18 117:7 153:8 154:5 164:9 165:8 provides 140:10 176:10 185:2 202:12 providing 72:13 156:2,4 public 1:18 12:17 24:4 50:4 53:4 96:13 104:22 105:16 115:17	123:3,4,19 131:16 131:18 136:17 153:13,17,20,24 154:1 218:18 230:2,21 233:19 publication 90:24 100:22 101:12,13 101:16 104:10 105:1 107:24 130:10 161:14,23 179:19 publications 90:11 90:12 91:10 101:3 101:5 102:20 103:16 160:12,24 161:4,8 publicly 62:23 103:20 105:11 163:12 publish 121:2,4 209:15 published 53:21 53:23 69:4,16 100:13 101:14 106:15,19 107:16 107:18,21,25 108:4 120:25 121:20 129:18 150:6,7 154:13 160:13,15 161:1,2 161:17 163:17 192:3 208:2,15,19 208:20 209:6,11 210:3 211:7,19,25 publishing 209:14 210:6,13,24 211:22 pull 164:17 171:3 222:23 pumps 176:15,15 176:16	pure 54:5 purified 174:4 purity 31:11,12 32:3,4,4 35:12,20 36:12,15,16 54:9 129:9 purpose 121:12 171:21 193:23 purposes 38:9 228:9,15 pursuant 1:15 76:9 77:14 115:3 204:16 pushing 176:16,16 put 24:5 27:7 29:3 40:8,16 41:15 46:12 69:11,12 81:24 90:1 93:25 103:23 144:6 148:12 157:20,22 158:20 170:8 191:6,22 201:7 puts 210:1 putting 64:18 83:4 83:5,6 148:12 162:24 puzzled 48:16 49:1
q			
q3a 202:10,20,25 204:12 q3b 202:10,20,25 204:12 qa 119:16 qualification 202:17,19 204:14 204:19 217:14 qualifications 90:8 91:25 qualified 68:16			

[qualify - recalled]

Page 34

<p>qualify 201:7 quality 22:9 25:6 31:11 32:3 35:12 50:18 54:1,2,6 98:17 161:16 171:23 195:5 quantification 143:9 quantified 174:4 quantify 206:1 207:14,19,21 quantifying 205:17 quantitation 49:15 question 11:21,22 11:23 13:3,7,8,12 13:25 14:3,5,7,19 14:19 15:6,12,14 15:25 16:7,9,15,18 17:3,7,8,10,15,18 17:23 18:13 19:25 20:11,16,17 21:11 22:13 23:2,23 24:16 25:3 26:14 26:15 28:9,14 30:19,23 31:3 32:22,24 33:4,21 33:21,24 34:2,6,9 34:14 36:5,14,22 36:23 37:4,11 39:17 41:23 43:7 43:7,20 44:10,13 47:20,25 48:24 49:1 52:12 53:19 56:6,7,14 58:8 60:9,10,11,15 61:10 62:5 65:25 68:20 69:15,15 74:14,16 75:16 76:5 77:9,13,18,19 78:8,9 85:10</p>	<p>86:21 88:2,3 91:3 94:16 100:20,21 102:2,3,12 106:3 111:11 113:15 116:21 122:14 128:6,7 129:3 131:13 135:6,9 139:19 142:3 143:6,6 150:12 151:8,18 153:18 153:22 155:4,8 156:25 157:2 160:22 162:17 168:11 169:15 172:21 182:18 184:6,20 192:7 196:21 199:3,18 200:11 207:16 209:4 210:15,20 211:11 212:4,7 214:19 223:1 questioning 199:21 225:21 questions 14:21,22 15:3 30:10,12 80:25 118:20 138:2 150:12,23 169:17 170:4,10 198:21 199:18 201:20 202:5 218:20,21,24 221:13 223:9 224:21 228:6,22 quick 118:7 122:16 180:13 228:24 quote 191:4 quoting 84:5 87:24</p>	<p>r r 2:1,17 3:1 4:1 5:1 6:1 8:4 63:13 230:1 232:3,3 r&d 69:2 rafferty 2:9 raise 10:10 75:8 raised 170:19 ran 120:18,18 205:12 ranitidine 57:14 57:22,24 58:3,7,10 58:19 59:12 60:3 60:19 61:6,16 62:9 101:21 102:1 103:18 104:4 121:25 122:12,25 123:2,9,11 126:8 133:18 161:19 175:7 raspanti 3:4 rationale 122:23 rbk 1:7 reached 140:2 reactive 137:15 189:12 read 16:20 21:23 22:15 25:2 30:2 30:18 31:6 33:5 35:9 40:13 54:12 67:22 86:14 105:9 123:25 125:16,17 150:18 191:10 192:9 226:18 231:9 233:5 reading 22:21 92:2 105:10,10 168:23 227:13 ready 51:21 64:20 90:20 91:16 111:1</p>	<p>reagents 27:23 28:6 real 128:11 228:23 realize 134:2 really 21:11 24:13 32:6,14 52:19 69:3 74:12 75:15 104:8 111:10 112:7 121:12 139:4 161:4 170:20 174:4,6,6,7 179:5,10 185:4 196:5,15 197:10 200:10 203:24 206:8 209:24 212:10 reason 73:2 213:20 231:11 232:6,9,12,15,18 232:21 reasonable 191:14 reasons 85:11 recall 70:11,18 71:1,7,8,13,21 73:6 108:17 109:13 118:22 120:5 124:10,22 127:18 131:23 133:15,16 144:14 149:3,4 150:8 153:10 155:22 156:8 157:17 158:1 163:10 165:9,15 192:4 202:8 216:18 223:8 225:12 228:5 recalled 123:18 138:13 149:5,6,8 164:11 165:7,18 166:9 167:20</p>
---	---	--	---

[recalled - remains]

Page 35

192:6 216:14 217:1,12,18 218:14 recalls 165:18 208:16,20 receipt 231:18 receive 63:22 160:11 received 65:13 81:21,21 83:25 90:10 119:24 181:8 receptor 93:17 219:24 receptors 193:17 recess 41:9,10 51:24,25 89:12,13 118:13,14 134:9 134:10 164:1,2 180:17,18 219:5,6 recipe 27:21 35:22 36:15 137:20 139:6 158:23 185:16 186:1 recipes 137:18 163:16 recognize 103:24 recognizing 29:17 recollection 144:12 recommendations 125:15 recommended 192:4,5 reconsider 77:12 record 9:2,11 10:1 17:4 27:4 34:4 39:12 41:5,13 44:1 45:24 51:6 51:15,20,23 52:3 52:22 57:3 59:18	75:10 80:12 81:14 134:8,13 144:4 170:9 180:16,21 181:17 191:6,10 192:18 201:8 210:22 215:16 recorded 9:4 recordkeeping 111:6 records 17:4 65:12 72:18,19,20 113:19,20 117:22 136:17 170:2 redepose 170:2 redirect 79:17 reduce 194:13 reducing 193:24 reefer 3:5 refer 20:9 25:4 45:11 49:12 56:4 145:1 179:25 195:3 221:5,23 222:2,16 reference 19:3 20:13,21 27:10,11 31:9,13,23 56:4 68:6,9 69:17 70:23 88:7 126:17 129:13 137:2,3 138:8,22 140:1,3 145:6 152:2 176:6 185:3 195:6 213:21 224:3 referenced 69:5 108:13 168:14 231:6 referencing 32:11 68:8 referring 35:14 41:1 45:1 68:21 69:7,24 125:21	203:13 227:3 refers 27:11,15 32:4 55:10 179:5 186:7 222:17 reflect 84:22 refresh 144:12 refresher 182:15 refreshing 84:4 refusing 17:6 regard 124:11 209:5 217:15 regarding 61:2 101:13 104:3,4 144:15 153:13 160:17 178:17 179:13 181:2 regards 9:4 register 108:23 registered 68:10 68:22 98:18 108:19 111:24 114:20 registration 108:21 109:4 regs 22:21 25:21 25:23 26:4 32:12 32:13 35:10 111:10 regular 136:3 regulations 19:10 26:7,23 30:25 35:2 36:10 37:1 48:17 111:21 112:2 134:21 regulatory 25:22 26:19 107:22 156:9,13 reiterate 189:22 relate 144:17 related 75:2 100:13,24 101:3	101:11,19,20 103:18 111:21 112:2 122:4 143:8 143:17 158:19 183:13,15 184:3 relates 1:5 102:9 112:25 116:14 relating 60:22 67:2 102:20 113:20 121:25 122:12,25 153:11 relation 75:4 relationship 171:19 relative 230:13,15 release 104:12,15 104:17 110:18,21 110:23,24 112:25 124:16 143:1 171:10 195:24 released 32:8 releases 110:4 116:4 releasing 110:25 112:9 relevance 75:14 relevancy 76:25 79:24 relevant 30:10 81:12 169:22 reliability 161:16 173:1 reliable 172:19 173:5 relies 171:16 215:22 rely 76:20 161:5 200:5 227:10 relying 77:3 163:2 remains 140:22 168:17 169:6,7,11
---	--	---	--

[remains - reviewed]

Page 36

169:12 remedied 109:25 110:9 remember 28:14 29:9 54:15 56:12 56:15 92:2 122:18 129:19,21 143:18 160:8 remotely 1:19 9:19,22 230:5 removed 124:17 render 15:22 16:4 rendered 14:11 renders 16:24 17:20 87:14 88:6 repeat 19:25 20:17 23:2,16 30:19 31:17 33:1 37:11 41:23 56:14 58:8 86:21 129:3 135:7 142:15 172:21 196:21 207:16 repeated 129:2 142:7 rephrase 184:6 report 25:2 26:9 26:12,16,17,18,21 27:2 28:11 31:3,5 31:7 33:5 34:20 82:23 83:2,5 85:1 87:23 88:22 89:1 90:15 119:17 145:17,21 148:9 157:15 158:4 159:4 169:3 175:1 186:19 223:14 reported 45:12 104:6 145:14 146:9,18,21 147:1 150:13	reporter 1:17 9:9 9:12,14,16 10:6,9 10:15 16:20 31:16 39:1 45:21 164:24 230:3 reporting 9:19,24 148:19 175:2,4,5,6 reports 61:6 62:2 75:22,23 76:1,1 115:11 131:23 141:1 represent 10:23 115:13 171:1 202:3 219:13 representation 53:22 representing 73:24,25 74:2 207:5 request 52:22 116:19,23 117:21 120:10 160:9 requested 16:19 31:15 66:9,9 169:19 require 18:4,9,21 19:13,16,17 204:9 required 14:21 18:13 23:8,9,11,13 23:19,25 45:6 179:1 213:12 233:13 requirement 19:10 23:7 25:13 25:17 26:5 31:2 37:8,12,15,18 43:12,17 44:22 45:5 46:7 107:19 134:23 135:24 136:2 138:10	requirements 19:21 20:2,19 22:25 23:5,10 51:3 107:17,19 108:6 136:7 137:14 157:16 158:6 requires 211:24 research 46:11 80:14 92:11 98:16 98:19 106:16,20 108:1,19 156:19 reservations 229:6 reserve 169:25 respect 116:18 123:15 129:13 209:7 210:12 respond 25:3 102:15 128:25 148:6 162:7 responded 13:25 15:25 16:7 17:3,8 26:15 36:13 104:7 response 100:16 102:24 199:17 responsibilities 107:22 159:19,21 responsibility 156:22 157:4 158:13,15,23 159:16 200:13 responsible 31:22 32:19 93:9 94:7 139:5 226:10,22 226:24 responsive 14:21 15:14 30:11 47:22 102:22 rest 91:12 restate 156:25 157:2 167:25	restroom 24:25 result 108:24 142:9 222:10,11 results 76:16 105:22,23 115:7 115:10 117:10,12 117:15 142:4 145:13 146:2,9,17 146:20 147:13 retained 56:9,13 56:16,17,20 57:13 57:21,23 60:5,20 61:2 73:8,11,12 74:4,9,20 84:24 157:8 186:19 retainer 65:18,21 66:9,12,15,17 67:17 68:6,21 69:5,8,10,20 70:2 70:7,20 71:5,9,16 72:6 81:20 return 231:13,17 revenue 64:9,10 revenues 63:16 64:1,22 65:2 review 38:20 52:6 52:21 82:18,21,25 83:3,4,14,15 101:12 108:6 161:13 162:10,13 231:7 reviewed 38:22 52:16 100:13,19 100:23 101:3 106:16,20 152:16 152:18,20,21,23 153:6,10 154:7,8 161:8,12,15,21,23 162:4,6,14,19,21 163:5,8,11,12 182:1,4,5,10
---	--	---	--

[reviewer - schaffer]

Page 37

reviewer 200:9 215:20 reviewing 83:18 83:20,21 84:3 reviews 82:7 200:9 rhone 159:23 riddell 5:10 right 10:10 15:23 18:19 20:8 22:16 22:17 24:5 38:12 42:23 49:21,24,25 50:11 52:13 54:18 54:19,21,22 55:1,8 55:18,23 56:10 57:12 62:14 66:3 66:6,10,18,19 67:21 68:1 69:25 70:12,21 76:25 81:4,11 82:8,9,11 82:12,15,19,19 83:11,12,16,17,20 84:6,8,24 85:21 89:4 90:6 91:1,6,7 91:25 92:5,17 94:15 95:2 96:7 97:14 98:7 104:19 105:3,20 107:6 109:19 111:17,21 114:19,24 115:9 115:16 117:8,23 121:7 126:3 127:11 128:22 130:1 135:3,19,20 137:4 139:2 140:4 140:13 141:9,21 144:10,18 145:9 145:12 146:2,4,19 147:15 154:21 155:22 156:7 158:7 165:15,20 166:1,4,15,20	167:5,16 168:15 169:16,25 175:1 181:11 182:20 183:25 184:24 190:4 202:14,22 204:17 205:19 207:6 210:18 212:17 213:6,9 214:8 215:2,3,24 216:9 217:24 221:1 222:15 225:11 risk 111:10 113:3 160:8,25 195:17 195:18,21,23 196:1,10,12,24 197:5,8,18 198:4 199:7,25 200:5,6,7 200:7,8 risks 196:19 199:9 rite 4:11 rlb 18:7 rld 18:25 19:11,22 20:4 25:19 128:2 128:10,15 130:14 216:13 road 4:8 5:6 robe 64:18 role 93:16 94:17 ron 1:9 7:3 9:4 10:8 48:20 66:25 211:6 230:5 231:5 232:2,24 233:2,4 233:12 room 9:18 218:22 rooney 5:18 root 196:13 rose 6:3 rosemarie 5:10 40:12 57:2,4 84:19	rosemarie.bogdan 5:12 rosemaries 57:4 ross 6:4 roughly 205:7 route 133:8 197:3 214:5,14 routine 195:25 207:2 rpr 1:17 230:19,20 rs 183:14,14 rubenstein 5:5 rubensteinb 5:9 rule 167:21,24 ruled 28:18,20,23 29:2 30:7 ruler 2:17 rules 1:15 ruling 191:2 run 92:21 132:3 175:20 running 121:10 131:12 205:18 207:11,17,23 s s 2:1 3:1,19 4:1,13 5:1 6:1 195:12 232:3 safe 18:1,1 19:17 19:19 36:1 46:6,6 179:7 safety 92:16,21,24 95:22 123:3 160:8 160:25 sak 1:7 sake 163:7 sale 13:20 sameness 25:24 27:10 31:8,19 34:22	sample 117:3 samples 114:3,9 114:10,11,14 115:8 116:8 147:13 san 92:4 sanctions 28:22 30:4,15 sanger 2:16 sartans 175:7 219:25 satisfied 112:20 satisfy 19:21 20:2 sausage 201:3 save 81:13 98:20 98:21 122:17,21 122:21 saw 87:11 131:10 131:24 142:12 145:10 193:11 saying 10:18 33:23 87:1 103:12 130:4 134:24 154:15 158:3 162:2 187:13 191:2 201:8 says 50:6 53:25 66:17,24 67:17 82:17 110:20 129:25 137:16 165:7 168:24 169:14 172:12 184:1 186:18 188:2 191:11,23 192:16 200:8 220:3,25 224:5 226:9 scale 159:22 scanned 182:17 schaffer 2:13
--	---	--	--

[scheduled - simply]

Page 38

scheduled 134:1 schell 2:5 scientific 100:23 161:14 scientist 92:11 scientists 161:15 162:6 scope 11:17 12:3 12:11,21 13:9 14:15 15:24 16:6 17:2 18:17 19:5 21:7 22:19 25:1 41:22 42:7 43:3,9 43:15,23 44:12,17 44:25 45:8 47:2 47:12 48:11,22 49:11 50:8 55:3,9 65:1 66:22 67:16 67:18 76:22 103:5 103:8 110:12 131:5,17,20 132:11 150:17,24 150:25 151:12,18 170:11 199:2,13 213:18 214:9 216:4,16 217:21 screen 40:24 41:15 48:4 87:15,19 118:3 157:20 164:20 scroll 219:21 222:8,13 223:11 se 43:17 search 50:22 209:1 second 27:1 40:6 42:19 46:17 51:4 67:15,15 74:22 87:11 105:7 109:16 124:2 175:16 180:11	182:15 198:11 199:21 secondary 109:24 secrecy 127:15 section 22:3,7 67:16 153:20,24 154:1 157:14,25 158:4 176:6 183:2 sections 108:6 155:1,1 sedran 2:13 see 11:7,21 17:5 40:4,10,21,23 41:3 42:18,20 43:19 47:14 48:4 51:1 53:11 66:22 67:24 69:24 76:12 88:23 90:11,24 91:9 94:15 101:24 102:12 129:4 132:1 133:10 146:18 150:6,7 158:1 163:20 165:4 176:7 180:7 181:24 185:11 188:4,6 192:15 198:6 205:20,23 206:10,25 210:6 216:21 219:23 220:2,3,4,6,7,8,25 221:4,6,21 222:9 222:24 223:23,24 225:25 226:5 seeing 131:24 160:8 223:9 seek 77:2 seeking 154:23 seen 24:19 39:23 46:15 124:8 131:19 153:4,6 154:4,8,18,20	185:18 192:21 210:2,17,23,24 211:6,7,18,22 sell 110:15,16 134:17 sells 136:25 sense 32:1,2 116:17 sent 38:25 39:14 142:20 162:2 164:24 181:10 231:14 sentence 68:17 125:10 separate 166:1 separation 176:20 september 56:18 165:8,15 served 102:18 103:4 services 98:16 192:17 session 14:20 set 22:9 45:22 46:25 69:18 88:10 175:18,19,19 203:18 205:18 207:12,19 230:11 settings 205:19 208:3 seven 147:13 150:25 198:7 share 40:4,16 100:3 164:20 172:12,13,14 181:23 shared 85:8 153:1 shareholders 62:25 63:15 shares 96:13	sheet 8:16 231:11 shit 185:12 shortly 88:22 shouting 133:7,8 show 24:6 26:16 26:18,21 50:22 91:7 157:18 173:25 178:1 186:25 188:25 192:14 194:9 219:12 223:25 showed 120:12 205:16 showing 87:18 129:22 147:20 187:3 216:22 225:13 shown 146:24 178:21 187:20 216:18 217:15 225:20 shows 183:21 194:2 221:2 222:10,14 side 84:18 113:14 170:5 sign 231:12 signature 69:13 85:22 230:19 signed 66:5 231:20 significant 214:1 silence 130:7 silent 130:5 similar 181:3 simple 17:18 206:14 simply 11:14,25 36:3,23 58:10 71:25 74:15 79:17 167:8 194:18 207:11 227:10
---	--	---	--

[single - stands]

Page 39

single 127:21 147:16 150:19 151:1 205:18,18 sir 10:18 11:21 13:3 14:1,2,3,4,17 15:3,14 16:8,17 17:7,10 18:20 22:20 24:13 25:3 26:9 30:23 36:2 36:22 39:23,25 43:20 44:11 46:16 47:17 48:16 49:3 50:6 53:20 65:25 66:22 69:15 87:17 92:20 100:12 105:9 150:4 154:21 sit 72:13 127:20 site 50:2 53:11 114:11 sitting 75:5 156:2 156:4 196:9 six 82:6 146:11 165:23 size 129:9 skilled 133:6 214:25 skincare 96:18 slack 2:16 slackdavis.com 2:19 slater 28:25 slow 174:15 small 40:24 53:10 smith 4:7 smoke 200:20 sneak 139:14 snippet 53:12 sodium 197:20,22 197:24,24 198:3 215:19	solco 3:16 sold 44:9 96:13 111:1 165:14 189:5 190:6,19 195:6 217:9,10 sole 63:14 solemnly 10:10 solutions 6:8 9:8 9:10 231:23 solvent 176:17,17 176:18 solvents 96:1 solving 94:7 somebody 73:9 114:5 180:11 209:17 sop 114:21 sop's 114:22 sorry 9:14 27:7 44:5 49:11 57:9 62:16 64:7,7 98:2 99:13 102:25 103:12 113:16 131:6 133:24 134:3 141:10 155:9,12 177:5 206:19 214:10 sort 37:22 74:12 75:10 86:19 104:2 122:14 124:21 127:6 133:22 141:20 161:5 168:21 171:19 174:22 179:16 197:10,13 sound 99:14 166:4 sounded 91:8 sounds 102:11 154:17 170:16 source 131:4,13	sources 213:4 south 2:10 space 131:10 speak 108:15 119:8 190:2 speaker 45:20 spec 176:25 177:21 178:3,3,4 specialized 106:10 132:6 206:3,6,22 207:1,25 208:7,8 208:11 specific 44:23 45:6 49:13 50:23 65:13 68:6,7 85:1 110:8 130:18 135:9 137:9,24 155:3,23 172:2 173:12,15 175:22 177:20 180:3 183:7,10 187:16 196:24 208:3 210:15 214:7 specifically 49:13 49:18 50:17 68:23 136:6,7 142:21 155:2 175:9 178:18 180:2 198:14 204:11 206:3 207:12,19 209:5 210:11 227:15 specification 47:10 134:24 135:12,23 191:17 specifications 8:17 22:25 23:5,13,19 50:4,16 specified 24:4 44:23 45:6	spectrometry 177:17 speech 29:5,13 speeches 108:5 spelled 26:3 spelling 63:10 spend 150:11 spent 82:14 83:18 84:6,15,22 162:21 spirit 158:19 spoke 23:15 sponsor 172:7 173:25 spot 66:18 stacked 79:24 stage 77:4 stand 68:3 standalone 95:2 98:10 standard 1:20 24:3 32:19 54:12 114:16 132:13 172:13,17 173:2 standardized 171:23 standardizing 171:22 standards 22:9 23:24 25:7 32:15 32:20 46:25 50:5 50:16 51:3 53:1,8 53:22 55:5 68:9 68:13 98:17 172:16,19 174:2,5 185:3 195:1,4,4,5 195:6,7 standing 221:12 stands 13:13 67:6 67:14,25 119:15 176:24
--	---	---	--

[stanoch - sure]

Page 40

stanoch 2:4	step 158:21,22,22	179:14,16 203:8	suggested 30:21
start 10:18 11:6	steps 191:14,15	204:21 215:18	111:3 143:15
72:23 81:25 95:4	steven 3:12 5:4	stuff 185:23	suggesting 42:11
96:9 156:3 220:22	202:3 203:5,6	styling 203:25	52:25 59:23 61:25
started 49:1 73:3	208:6 211:10	subject 102:16	72:13 115:19
92:15 93:19 94:25	212:4 214:18	108:24 117:14	suggestion 79:11
96:14 115:18	218:5	145:3 165:14	suggests 50:15
140:9,11,15 181:9	steven.hunchuck	229:6	152:4
starting 34:2 54:8	3:15	submission 192:11	suitability 176:8
92:12 96:16 173:9	stock 63:3	195:11	188:5
174:7 186:6	stop 14:17 30:14	submissions 99:16	suitable 226:15
188:17	33:3 64:20 169:1	153:16	suite 2:14,17 4:8
starts 157:25	191:19	submit 97:3,5	4:17 5:6,20 6:4
212:13	storage 111:9	99:11,25 108:22	summaries 117:4
state 1:18 4:4 10:7	113:2,14	122:25 123:14	summarize 86:23
69:21 87:5 89:2	stored 206:15	155:14 161:25	summary 90:8
104:24 204:20	stories 201:19	162:1 196:11	91:25 104:2
227:9 230:3	story 104:8	209:21	145:17
stated 24:2 89:3	stoy 3:5 40:6,14	submitted 82:6,13	summer 46:2
117:1 140:14	143:25 164:19	85:4 97:7,8 99:9	superior 1:15
151:14 189:10	strategy 113:4	100:21,22 101:15	supplier 18:4 74:1
statement 24:15	street 2:5,10,14	161:8 192:19	suppliers 58:18
50:3 98:15 122:17	3:6,19 4:4,13 5:15	196:2	59:5,9 80:21
217:23,24	5:20	submitting 124:3	supplies 171:22
statements 115:17	strength 22:8	156:6	support 61:1
215:10	31:11 32:2 50:19	subscribed 233:14	99:18,20 148:22
states 1:1 9:6	54:9 129:9	subsequent 204:12	supported 147:23
10:25 13:20,20	strictly 202:25	substance 11:13	148:17
22:24 23:4 95:18	strike 28:13 29:10	12:22,23 14:8	suppose 101:23
151:22 165:14	30:5,14 58:2	15:16 94:3 159:20	supposed 24:23
206:8 227:18	178:6 208:6	171:10 202:14	221:14
stating 10:1 58:19	stroll 226:4	207:12 213:14	sure 20:18 23:3
86:18 215:15,17	structural 133:2,3	substances 96:4	25:15 50:10,23
stationery 176:20	133:5,9 158:24,25	sudden 196:8	51:6 58:9 63:12
status 108:19	185:6 186:1	sued 58:18	67:24 82:24 86:25
112:16 119:1,12	197:13,14,16	sufficient 19:18	88:25 109:22,23
statute 41:21	214:15,15	109:23	110:1 113:5,7,18
stay 27:4	structure 31:25	sugar 193:12	117:13 120:21
stenographic 9:11	203:6 212:24	suggest 51:2 86:17	135:11 136:10
stenographically	structures 37:24	87:12 125:25	139:20 140:15,19
230:10	139:8,10,11		141:14 142:25

[sure - testify]

Page 41

157:19 163:23 164:14 168:10 172:22 179:7 191:22 196:23 surprised 152:11 153:2 170:15 suspected 49:14 swear 9:12 10:11 swedesford 4:8 switch 56:2 sworn 230:5 233:14 symposium 108:9 108:15 160:20 179:12 synthesis 27:13 54:3 93:12,16 94:17 96:23 133:7 159:13,19 163:16 177:24 185:5 191:15 214:6,14 215:5 217:5 synthesize 18:23 94:12 96:25 synthesizing 97:18 158:13,16 synthetic 18:6,14 18:24 19:19 20:24 133:8 137:17 159:6,9,13,21 177:24 185:25 191:15 197:3 syringe 197:7,8 system 113:9 119:5,5 171:23 176:7,8 177:9 187:22 188:2,4,16 209:23	t t 230:1,1 232:3,3 tab 181:13,19,24 182:13,14 table 47:9 54:15 54:17 55:21 197:18 tablet 54:24 55:8 134:22 147:17 222:11,11 tablets 70:9 182:7 183:8 take 24:7,25 26:20 41:3 49:23 50:13 52:6 87:20 89:6,8 92:19 95:22 112:21 118:6,8 125:20 133:25,25 134:3,6 141:8 144:11 163:19,22 167:1 174:19 180:13 203:14 218:7 219:1 222:22 225:11 228:3 taken 1:15 41:9 51:24 89:12 109:8 118:13 134:9 164:1 180:17 219:5 230:10 takes 131:11 talk 24:14,14 32:9 52:13 61:24 121:16 125:11 141:17 185:21 199:15 203:15,16 talked 17:13 41:18 81:18 108:18 118:21 129:15,17 134:20 163:1	talking 15:8 16:17 33:3 38:9 39:11 40:6 45:3 54:23 121:24 212:13 talks 32:16 227:15 tangential 171:19 team 67:10 104:3 196:16 tear 185:10 technical 176:12 technique 176:2,2 technologies 32:18 227:11,17 technology 32:18 179:6 187:11 227:16 tell 42:25 50:5,14 53:20 56:25 58:21 64:1 72:14,19,21 74:15 77:20 90:3 100:6 113:18 119:24 122:16 125:20 126:2 127:21 136:16 140:17,25 141:13 155:19 167:4,17 169:12 184:25 185:23 186:21 224:13 telling 40:22 49:24 62:3 111:23 122:19 tells 206:17,17 ten 89:8 99:23 118:8,10 134:6 163:22 203:22 tensin 93:17 term 26:6 30:20 30:25 35:5,17 36:3,5,6,9,23,24 38:3,5 41:21,24	141:4 202:16 terminology 110:25 terminus 5:6 terms 72:15 91:23 103:5 137:18 138:15 149:25 162:25 173:1,5 198:8 test 50:20 71:21 110:20 114:18,23 115:7,10 116:6,6 117:4,11 120:22 121:4,9 130:23 131:3 132:6,7 133:1 145:13 147:13 175:10 176:11 177:17 179:2 180:3,6 187:17 188:15,17 188:18,21,24 203:11,17 204:6,8 204:21 205:15,18 206:22 207:17,25 209:16 215:12 224:16 tested 68:16 71:14 72:1,15 78:20 115:8 120:21 132:21 133:13 138:10,11 140:23 142:21,22 145:18 146:22 147:4 166:7,18,22 167:4 174:4 223:20 testified 200:14 204:23 205:10 214:24 testify 107:7 227:24,25 230:6
---	---	---	--

[testifying - time]

Page 42

testifying 79:7	184:16 186:19	124:20 133:22	227:13
testimony 10:11	187:5,15,18 194:1	140:8 150:10	thinking 189:24
16:19,23 36:4	194:6,9,15,18	160:6 164:7	208:11
50:8 56:10 60:5	195:24 198:18	194:14 218:9	third 57:6 142:22
60:22 61:17 72:10	203:16 204:15,24	think 10:19 16:1,1	142:24 153:23
72:12,14 81:5,7	206:3 208:14,25	25:4 29:17 38:25	183:3
103:6 135:11	209:2,25 212:9,14	39:2,16 40:7,16	thomas 2:9
141:12 150:4,13	213:12 214:7,20	43:16 54:14 56:17	thornberg 4:12
153:4 154:4,17	214:21,22 217:2,4	57:11 58:24 59:1	thought 44:5
156:4 190:11,24	219:17 223:18,22	59:3 61:25 66:8	60:14 61:22 65:9
192:22 213:11	testings 194:22,24	72:25 73:5,19,20	87:24 143:15
214:4 215:8 230:9	tests 54:10 79:22	74:23 75:1,2,4,11	196:22 223:5
231:9,18 233:8	175:22,22 194:5	75:16,19 76:15,18	thousand 205:7
testing 44:24 45:7	196:18,25 199:7	77:11,15,17,18,20	thousands 117:17
67:18,19 69:21,22	199:24 200:3	77:23 78:25,25	threatened 28:22
70:3,7,8,13,15,20	203:17 207:11	79:12 80:5 81:2	threatening 30:4
70:22 71:4,9,19,24	224:18	81:12 86:24 88:23	30:15
72:4,7,9,24 73:3,9	teva 5:2,2 117:24	91:22 92:7 98:13	three 5:14 92:23
73:13 74:10,20	162:19 202:4	99:13 101:25	120:24 158:22
75:18,22 76:10,16	207:5,8 229:9	102:3,7,23 104:15	threshold 202:17
76:20,22 77:25	thank 10:15,22	109:2 116:3	202:19,25 204:14
78:4,5,10,12,14,16	16:21 42:16 47:13	119:14 120:17,25	thursday 1:19
79:4,9 80:1,5,6,9	54:16 66:21 91:1	121:17,21,21	tiktok 185:17,18
80:14,23 81:7,8	105:8 116:16	122:1,9,10 123:16	185:20 186:4
93:13,17 94:18	138:3 164:22	123:17,18 124:12	time 1:20 9:2
96:24 105:12,17	165:2 175:16	124:13,15,15,16	26:21 37:4 39:1
108:1,2,2,3 110:4	183:6 201:20,22	124:20 127:11	41:7,12 51:22
110:6 112:25	218:19 223:5	131:22 132:1,3,12	52:2,6,21 70:1
113:21 114:8	229:2,10,11	135:11 137:21	78:5,9 82:6,14
115:3,19,20 116:7	thanks 128:6	142:8,25 143:2,5	84:2,15,22 85:3
117:4,19,25	therapeutic 26:1	143:19 144:14,16	89:1,10,15 90:3
119:23 120:1,23	31:23	146:22 151:2,7,18	97:17 105:14
121:5 124:25	thing 33:1 43:19	152:25 157:14,24	109:2 115:21
125:3,6 130:18	51:1 62:5 65:4	157:25 158:4	118:11,16 123:4
131:9,15 136:10	121:3 150:19	166:2 169:18	134:7,12 150:11
136:15 140:11	164:13 192:2	170:8,21 175:4	153:23 159:10
141:21,24 142:4	197:19	181:8 188:9	160:5 161:16
145:7 146:1,25	things 26:2 28:24	189:23 190:3	163:24 164:4
147:23 151:2	29:18,25 40:8	192:12,18 211:10	169:17 170:9,18
174:20 175:24	68:17 69:2 85:13	212:2,7,14 213:17	174:10,10 180:15
179:21 180:5,5,9,9	112:21 117:14	214:1,25 220:18	180:20 186:16

[time - unacceptable]

Page 43

188:8 197:2,3 198:6 201:15,21 204:1 218:25 219:3,8 221:13 229:12 230:10 231:19 timeframe 231:8 timeline 121:4 times 129:3 146:11 149:10 190:12 198:15 212:7 timing 141:13 170:20 tiny 165:5 206:2 title 226:1 tobacco 200:20 today 11:6 14:12 22:5 32:18 38:9 48:8 61:23 72:13 75:5 85:12 95:5 95:12 103:6 112:17 127:20 138:16 156:2,4 160:4 169:8,13 202:6 today's 83:22 84:3 229:13 told 39:4,5 45:22 54:15,17 56:8 105:19 125:19 127:24 128:3,7 134:15 135:12 138:5 139:24 142:9 143:2 145:25 151:25 161:7 190:2 tomorrow 169:9 top 67:7 79:24 127:18 133:14 165:6 219:22,22	220:2 222:9 topic 160:7,25 161:7 212:15 topics 149:24 160:12 161:1,2 198:12 torovastatin 218:7 torrent 162:19 total 47:4 64:1,10 186:11 touched 198:22 tower 5:19 toxic 21:20 49:15 96:4 134:25 218:2 toxicologist 106:7 106:8 161:4 168:6 193:18 toxicology 107:15 track 86:22 trade 5:20 train 196:22 trained 208:7 training 106:11,23 transcript 1:12 30:2,18 230:9 231:6,20 233:5,8 translates 54:20 traurig 5:4 tried 184:20 trischler 3:4 7:4 10:2,2,17,22 12:5 13:10,16 14:24 15:7 16:21 18:18 18:21 22:14 27:6 28:12,20 29:4,8,15 29:20,23 30:1,9,16 31:24 33:14,18,23 34:5,12,15,18 39:19 40:5,20 41:6,16,17 44:11 46:12 48:23 51:16	51:18,19 52:4 53:13,17 57:17 59:17,22 60:14 61:9,13 64:16 65:4,14 73:19 74:25 75:6,21,25 76:4,7,12,24 77:20 78:2,6 79:2,6 80:3 80:11 81:11,17,24 89:6,17 90:1,21 92:19 102:3,6,16 102:25 103:7 118:18 133:24 134:14 142:11 143:22 144:6 148:1,4 149:21 150:1,20 151:7,13 155:12 157:21 163:19,23 164:6 164:15,22 165:2,3 169:16 170:7 199:1 218:23 221:11,18 222:3 223:4 224:25 225:4,10 226:20 227:12 229:5 true 11:15 12:1 44:6,7,14 59:13 90:7 105:24 107:4 150:23 152:4 199:9 230:9 233:8 truth 10:12,12,13 230:6,6,7 try 13:18 23:17 33:4 34:12,15 40:14 97:11 138:1 144:20 164:19 trying 24:24 61:9 62:6 74:25 75:7,7 75:8,15 77:1 86:23 88:3 121:3	135:10 138:15 144:25 154:3 171:22 179:8 207:20 211:10,13 218:14 tuned 206:4 tunnel 95:25 199:12,19 turn 66:21 153:2 twenty 132:23 two 34:3,3 82:14 83:13,18 86:15 88:19 89:2 91:9 91:20 92:22,22 109:10 120:24 139:24 158:22 162:25 176:16 219:24 tx 2:18 6:4 type 74:20 75:17 132:2 206:9,10 213:13 types 185:15 212:24 typewriter 206:9 typewriters 206:11 typically 37:19 46:9 71:23 148:11 223:19
u			
u.c. 92:8 u.s. 3:16 6:3 uh 91:19 182:24 ultimately 209:25 ultra 188:7 ultraviolet 205:21 205:22 unacceptable 226:12 227:9			

[uncommon - valsartan]

Page 44

uncommon 19:1	202:7 204:14	45:6 46:1,10,10,20	v
undergraduate	205:12	46:25 47:18 48:2	vague 32:13
178:5	unit 9:3 164:5	48:8,17 49:12,16	validate 50:20
underlies 147:21	219:4	49:23 50:4,10,15	54:11 141:25
underlined 31:12	united 1:1 9:6	51:2 52:23,25,25	209:20
underlying 214:5	10:25 13:20,20	53:3,7,21 55:4,10	validated 119:6
undermines 77:6	22:24 23:4 95:18	55:17 129:18,22	145:13 146:1
understand 11:2	165:14	129:24 130:10	147:24 209:3
14:19,23 15:2,4,9	university 92:4	134:23 135:12,23	validation 113:1
15:13 20:11 58:1	207:3	171:4,6,11,14,17	117:4 119:8
58:4 59:6 62:13	unknown 44:8,15	171:18,19,20	valisure 8:15
65:18 68:19 72:10	44:18 47:10,19	172:1,5,7,11,12,15	116:3,19,24 117:5
72:12 74:14,25	54:18 55:7,20,21	172:18,22 173:3,4	117:21 119:23,25
75:6,9 77:1 81:16	55:24 126:16	173:8,21 174:5,9	120:6 121:10,21
89:20 98:13 107:2	129:25 130:2	174:12,17,22	121:24 122:9
110:11 135:6	134:21 202:24	175:2,5,9,11,15,20	123:18 124:7,14
138:4,15 139:16	204:15	175:23 177:15	140:11,16 141:13
139:20,21 154:3	unopened 39:16	179:9 181:13	141:18,24 142:5,9
159:13 165:12	unreliable 162:3	182:1,5,10,19	142:19,22 143:8
216:7 217:13	unsafe 18:2	183:14,15 185:2	143:16,23 144:8
218:15	updated 174:10,13	185:16 188:8,8,9	145:7,18 146:12
understanding	227:15	193:12 195:7	147:24 148:8,18
54:4,5 58:11	uploaded 143:25	209:25 225:14,16	148:19 152:4
77:24 110:14	upper 182:22	225:21,25 226:21	208:2 216:18
113:11,17 152:9	urgent 175:4	226:25 227:8	223:8,20
166:10,11 171:25	url 226:5	usp's 25:4 46:23	valisure's 142:7
172:4 173:20	usa 3:10 5:2	usp.com. 25:11	216:22 217:2
184:7 221:8 223:7	use 18:6,10,13,22	usp.org. 53:3,11	valsartan 1:3 8:13
226:10,22,25	40:15 78:15 96:7	usual 66:12	8:17 9:5 11:1 45:2
understood	133:9 137:20	usually 172:15	46:1 48:9,15 56:9
103:13 135:11,21	171:8 175:25	utilize 120:22	56:13,16 57:25
undescribed	177:16 178:2	utilized 171:6,12	59:10 60:2,19
126:16	184:16 187:6	171:14	61:6,16,18 62:1,10
unexpected 19:1	189:18 193:2	utilizes 172:1,3,5	65:2,2,13 66:2
unfair 75:7	197:21 206:9,9	uv 176:9,23 177:2	67:2,18 69:21
unfold 94:22	useful 176:13	177:4,6,7,8,10	70:4,7,8,9,12,14
unfortunately	user 110:2,8	178:1 187:19	70:16,22,24 71:9
187:11	usp 22:23 23:3,7	188:1,5,6,16	71:10,17,19,21
unidentified 44:8	23:17,23 24:2	205:21	72:4,5,7,9,15,24
45:20 135:13	25:5,9,10,11,18,21		73:3,6 74:6,9
184:4,12 186:10	25:22 27:17 44:23		76:21 78:20 79:9

[valsartan - whatsoever]

Page 45

79:19 80:6,15,18 80:20 81:19 84:23 85:5 93:18 94:19 101:11 102:2,10 105:12 113:21,25 114:8,11,14,19 115:7,14,19,20 116:1,6,11,15,18 116:23 117:18 119:21 120:1,8,14 120:20 122:1,2,4 123:9,15,18 124:8 124:11,13,15,17 124:19,24 132:16 133:7 136:11 137:19 138:19 140:12 141:8,19 141:25 142:6,20 143:9,18 145:18 147:22 150:15 151:23 152:6,7 153:11,12 159:14 164:10 165:7,13 165:18 166:6,23 168:1 171:4 173:13 181:14 182:2,6 183:8,14 183:15 184:3,18 184:23 187:2 189:2,5,18 190:5 192:25 193:6,23 194:3,3,13,20 203:21,22 204:5 215:5,12 216:19 216:23 218:6 221:5,5,6,9,24 222:1,6,23 223:23 224:5 228:12,18 231:4 232:1 233:1 variability 129:9 129:12	varies 66:14 various 27:21 45:15,18 47:6 84:4 108:12 110:1 123:7 175:18 178:17 193:13 203:17 218:9 vast 170:11 vaughn 57:8,9 vents 176:16 verify 231:9 veritext 6:8 9:8,10 231:14,23 veritext.com 231:15 version 42:21 91:4 victoria 5:5 video 1:9 9:3 27:4 34:4 40:1 41:13 51:23 52:3 134:13 180:16,21 185:17 185:20 186:4 videographer 6:8 9:1,9 27:3 39:25 41:4,7,12 51:14,22 52:2 89:10,15 90:18 91:15,20 118:11,16 134:7 134:12 144:2 163:24 164:4 165:1 180:15,20 181:17 218:21 219:3,8 220:10,15 220:20 223:3 228:23 229:4,12 videos 185:18 videotaped 1:12 view 46:23 104:22 198:16 200:14 violating 188:10	violation 111:20 violations 112:1 violet 188:7 virtually 14:12 vis 148:9,9 visit 95:22 vitamin 123:24,24 voluntarily 199:16 volunteer 199:3 volunteered 150:20 w w 5:20 wait 88:25 155:7 waive 9:23 73:17 walker 3:18 walnut 2:14 walsh 5:13 walsh.law 5:16 want 17:14 25:2 30:16 33:1 34:10 39:6,9 49:18 51:1 51:12,17 60:15 64:12 76:24 81:14 86:25 90:19,20 103:1 113:7 121:16,19 123:5 123:25 125:9 139:15,15,20 141:2 142:24 143:20 155:24 163:20,21 164:8 175:4 190:16 191:20 193:4 199:11 201:17 204:11 214:18 219:20 221:15,16 226:8 227:14 wanted 52:6 54:24 81:20 91:12 113:13 116:5,6,8	118:19 120:7 138:14 wants 51:20 warn 198:8 212:8 212:12 warned 142:22 warning 112:13 178:16 warns 180:2 watch 215:17 water 200:23 201:11 way 2:17 34:10 60:17,17 139:6 143:17 149:24 150:11,24 151:3 190:16 213:16 221:13 224:16 wayne 4:9 we've 29:3 72:8 105:17 109:10 170:9 186:23 187:12 195:21 wear 200:19 website 25:4,9,11 49:12,24 50:11 52:23,25 53:5,12 104:16,17,20 225:14,16,22 week 82:11 171:8 weight 32:1 206:17 welcome 29:21,23 30:17 went 52:21 55:20 88:19 92:10 198:4 199:2 west 4:17 whatsoever 76:21 79:13 110:3
---	--	--	---

[whiteley - zoom]

Page 46

whiteley 2:3,5	141:13 142:1,7	205:9 214:12
wife 63:2,5,17	163:13 171:7	year 82:8,15 96:12
95:11	186:22 193:21	163:18
william 6:8 9:7	208:1 225:25	years 64:9 92:22
winded 28:9	worked 94:1,4	92:23 99:23
window 179:17	156:9,13,15,21	120:14 171:21
witness 1:13 7:2	157:3,6 169:20	174:20 203:22,23
9:12 10:6,8,14	working 59:13	york 5:11
11:3 14:25 15:5,9	60:4,7 85:5	youtube 108:12
15:11 17:22,23	101:20 119:4,6	z
29:12,19 34:1	127:9,13,16,19	zantac 132:18,21
40:19 51:12,19	140:11	161:19 175:7
59:20 67:1 79:7	works 172:7	zero 55:12 88:17
80:13,24 91:18	world 95:19	129:23 130:8,8
102:19 107:3	105:20 128:12	135:25 136:7,11
115:24 118:10	130:17	137:14,17,21
128:25 148:5	worldwide 96:8	138:8,8,12 139:4
151:14 164:18	worried 186:1	140:4,4 147:23
168:12 169:17,20	worries 144:24	148:16 149:10,13
169:22,24 170:3	worry 60:18	149:15 152:3,6
181:15 199:2	worth 82:14	166:13,19 168:2
214:11 231:8,10	write 125:13	168:22 169:14
231:12,19	written 48:17	189:12,23,24
witnesses 7:1	130:9,11 131:21	192:6,7 205:3
17:13	wrong 110:15	216:9 218:6,10
word 34:21 86:10	162:7 189:4	zhejiang 3:16
206:12 208:6	197:17 198:4	zhp 70:17 131:8
221:2 227:22	211:23 212:3	152:12 162:13,14
words 33:7,10	wrote 104:3	215:24
34:3,4,19 86:10	x	zhp's 152:10,10
220:6	x 1:3,8	zmick 4:16
work 38:19 58:9	y	zoom 1:19 56:24
63:19,23 64:2,23	y 63:13	
65:13 66:22 67:18	yards 45:14	
68:12 76:14 77:15	yeah 47:14 86:23	
81:19 85:4 92:11	87:2,4 118:8	
96:23 112:10	138:14 145:2	
116:14,15,17,22	183:9 187:21,25	
117:5,11 119:21	187:25 197:1	
120:15 123:1,8,10	198:20 200:11	
123:11,12 127:5		

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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